United States Court Of Appeals for the Federal Circuit

NUVASIVE, INC.,
Appellant,
v.
WARSAW ORTHOPEDIC, INC.,
Cross-Appellant,

2015-1049, -1050

Appeals from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2013-00206

- -

WARSAW ORTHOPEDIC, INC.,
Appellant,
v.
NUVASIVE, INC.,
Appellee,

2015-1058

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2013-00208

NUVASIVE'S CORRECTED OPENING BRIEF

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February 19, 2015

CERTIFICATE OF INTEREST

Counsel for Appellant NuVasive, Inc., certifies the following:

1. The full name of every party represented by me is: NuVasive, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: N/A.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Fish & Richardson P.C.: Frank E. Scherkenbach, Stephen R. Schaefer, Michael Hawkins, Stuart Nelson, Michael J. Kane, Craig E. Countryman

Dated: February 19, 2015

/s/ Craig E. Countryman
Craig E. Countryman

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STATEMENT OF RELATED CASES

Pursuant to Fed. R. App. P. 47.5, counsel for NuVasive states that there has been no prior appeal to the Federal Circuit in these *inter partes* review proceedings of U.S. Patent No. 8,251,997.

The current appeals are related to a set of prior appeals in a litigation involving U.S. Patent No. 5,860,973, which stems from an application in common with the '997 patent. All the appeals involve overlapping issues, including the validity of Warsaw's patents in light of the Brantigan prior art. Those appeals were *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Nos. 13-1576, -1577, and they were argued on December 1, 2014 to a panel of Judges Lourie, Dyk, and Reyna. No decision has yet been issued.

These appeals are also related to a district court case in which Warsaw has asserted the '997 patent against NuVasive—*Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-02738-CAB (MDD) (S.D. Cal.). The claims and counterclaims in that case related to the '997 patent are currently stayed pending this appeal.

STATEMENT OF JURISDICTION

These are three consolidated appeals from final written decisions of the Patent Trial and Appeal Board of the United States Patent and Trademark Office in two *inter partes* review proceedings, both concerning Warsaw's U.S. Patent No. 8,251,997, IPR2013-00206 and IPR2013-00208. The Board issued its final written decisions in both IPRs on July 10, 2014. (A1-37; A45-80.) The Board denied NuVasive's petition for rehearing in IPR2013-00206 on August 28, 2014. (A38-44.) NuVasive filed its notice of appeal in IPR2013-00206 on August 29, 2014. (A4850-52.) Warsaw filed its notices of appeal in both IPRs on September 9, 2014. (A4855-57; A9642-44.) All these notices were within the 63-day time limit set by 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1). This Court therefore has jurisdiction over all these appeals under 35 U.S.C. § 141(c) and 28 U.S.C. § 1295(a)(4)(A).

STATEMENT OF THE ISSUES

1. Whether the Board erred in finding claims 9-16 and 24-30 of the '997 patent non-obvious where:

   a. The Board legally erred by rigidly focusing on whether the Michelson '247 prior art expressly taught or suggested a claim limitation regarding a spinal implant's length;

   b. The Board failed to consider whether it would have been obvious for the skilled artisan to select an implant of the claimed length given his familiarity with Michelson '247, and his general knowledge, experience, and ordinary creativity;

   c. The Board ignored the fact it had already found that another prior art reference disclosed the very length limitation it found missing in Michelson '247; and

   d. The Board erred in interpreting Michelson '247 and comparing it to the claims.

2. Whether the Board's judgment that claims 9-16 and 24-30 are non-obvious should be vacated where its final written decision, which changed its interpretation of Michelson '247, did not address two other proposed grounds that included a reference explicitly disclosing the length limitation but had previously been deemed "redundant."

INTRODUCTION

NuVasive is appealing an overly rigid and formalistic obviousness analysis by the Board. The claims cover a method for spinal surgery by approaching a patient's disc space from the lateral direction and using a series of tools to remove a bad disc and to replace it with an implant of specified length. The Board correctly found that the prior art disclosed the claimed lateral approach and tools, and that the skilled artisan would have combined them with references disclosing the implant. The Board also found, when invalidating other claims, that the prior art Brantigan patent disclosed an implant with the claimed length. But the Board's sole basis for upholding the validity of the claims at issue in NuVasive's appeal was that the prior art Michelson '247 patent (part of the combination asserted against those claims) supposedly did not expressly disclose or suggest an implant with the claimed length.

That was legal error. Both *KSR* and this Court's decisions have cautioned against finding non-obviousness simply because no prior art includes an express instruction to arrive at the claimed invention. Instead, the Board must consider whether a skilled artisan—with his knowledge, experience, and creativity—would have found the claimed invention obvious. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). The Board thus erred by confining its analysis to the express words of the prior art Michelson '247 patent, and compounded that mistake with factual

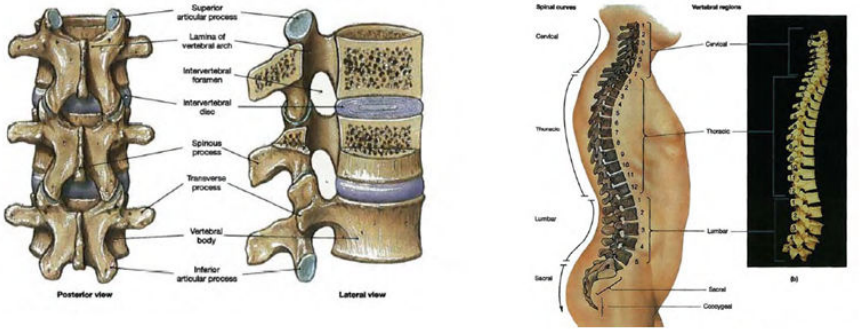
errors in interpreting it. After correcting these errors, this Court should reverse or vacate the Board's non-obviousness determination.

The Board also erred in its treatment of a set of alternative invalidity grounds NuVasive included in its petition. There were serious questions about whether the '997 patent claims were entitled to the 1995 priority date that they sought. One examiner, in a prior reissue proceeding involving the '997 patent's parent, determined that materially similar claims were not entitled to the 1995 priority date. So NuVasive presented alternative grounds in its *inter partes* review petition demonstrating that, if the Board agreed with the reissue examiner's priority assessment, then the '997 claims were invalid based on intervening prior art that had emerged between 1995 and their 2011 filing date. The Board's institution decision concluded these alternate grounds were "redundant" because it thought the pre-1995 prior art sufficiently taught or suggested all the '997 claim limitations. But, then, in its final written decision, the Board changed its mind and determined the prior art Michelson '247 patent did not disclose an implant of the claimed length. That was wrong on the merits, as discussed above. Nevertheless, it should have put the alternative grounds back in play—one of the intervening references expressly disclosed a lateral implant with the claimed length, so it could no longer be "redundant" given that the Board's reinterpretation of Michelson '247. The Board thus legally erred by not reassessing the alternative grounds in its final written decision, and, at a minimum, this Court should remand with instructions for the Board to consider those grounds.

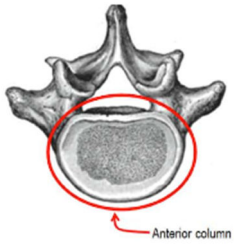
STATEMENT OF THE FACTS

I. The Prior Art: Methods for Performing Lateral Spinal Surgery With Various Tools and an Oversized Implant Were Well-Known.

The patent-in-suit relates to a method for performing spinal surgery. The spine includes a vertebral column composed of a series of bony vertebral bodies separated by spongy discs. (A306-07.) The left two images below show part of the spine from the back and side, respectively, while the right images show the entire spine.

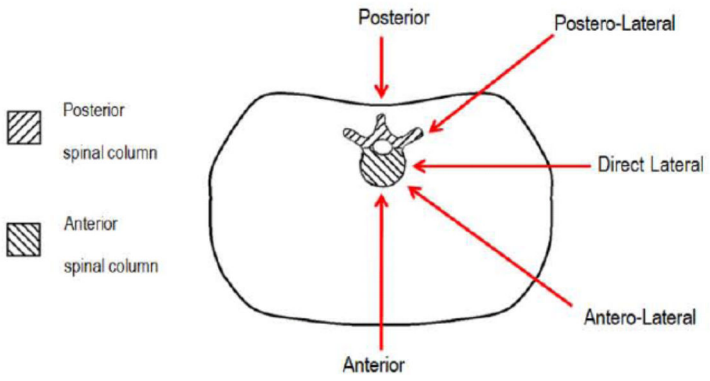


Each disc sits between two vertebrae in an area known as the anterior (front) column of the spine, a top view of which is shown below. (A307.)



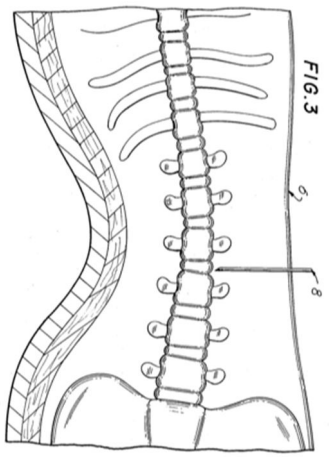
The discs can deteriorate, bulging into surrounding tissue or irritating nearby nerves. (A306-09.) One treatment is fusion surgery, in which all or part of the disc is replaced with an implant that facilitates stability and bone growth between the adjacent vertebral bodies and through the location where the disc once resided. (*Id.*)

A surgeon has to consider at least three issues when performing a spinal fusion surgery. The first is where to make the initial incision, and from which direction to approach the disc in order to remove it and replace it with an implant. Surgeons had developed a variety of techniques from approaching the disc space, including from either the patient's front (anterior), back (posterior), or side (lateral). (A306-09.) Other surgeons approached the disc space at an angle, including the postero-lateral and antero-lateral approaches. The figure illustrates the variety of known approaches.

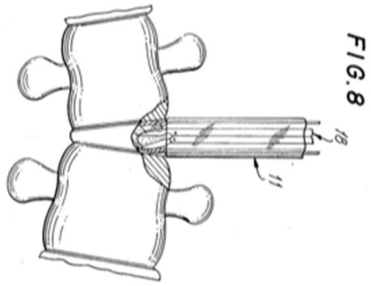


The attraction of the lateral approach was that it avoided the danger of contacting either the aorta or the spinal cord, which were, respectively, the risks of anterior and posterior approaches. (A308-09.) But the lateral approach had problems of its own—the lower lumbar spine is surrounded by a nerve-dense muscle called the psoas, and it was difficult to navigate the psoas without contacting a nerve and causing severe injury including paralysis. The psoas was less of an impediment to surgeries in the upper lumbar spine, however, and some surgeons had long taught and relied upon lateral procedures in those regions.

An early prior art example of a lateral approach to the spine for performing procedures such as a discectomy (removal of the disc) and spinal fusion was found in a patent to Dr. Robert Jacobson filed in 1982. (A477-91.) Jacobson describes a lateral procedure in which the surgeon makes an incision on the patient's side, and then a "needle 8 is inserted laterally through the patient's side," as shown in Figure 3, reproduced below (and rotated 90 degrees). (A487 at 5:28-46; A479; A317-18.)



The surgeon then advances a speculum with a larger diameter over the initial guide needle to widen the surgical path, and then a final working cannula within the speculum, after which the speculum is removed. (A487 at 5:45-6:13.) At this point, "the cannula may act as an instrument conduit" for a number of surgical procedures, including a "fusion." (*Id.* at 6:9-13.) Figure 8, reproduced below, shows the cannula (11) inserted between two vertebrae from the lateral direction, with forcepts (18) inside it that can scoop material out of the disc space. (A488 at 7:40-50.) The cannula could be anchored in place while the surgeon was working by using "sharp tines affixed to the cannula tip." (A489 at 9:41-42, 10:1-6.)



A second issue that surgeons had to confront was what tools they should use to create the corridor to the disc space through which they could replace the disc. By the early 1990s, surgeons had devised an alternative way of accessing the disc space called sequential dilation, which caused less trauma to the patient's tissue. (A318-320.) The surgeon would insert a series of cylindrical instruments with gradually increasing diameter, and thus slowly expand the patient's tissue to create a larger operative corridor. (*Id.*) A 1992 article by Leu exemplified this approach. (A495-506.) Leu describes a fusion procedure in which "[o]ver a central guide needle," like the one in Jacobson, "four cannulas of stepwise diameter are stepwise overslipped, one upon the other." (A498.) Leu recommends using its procedure with implants, which it calls "composite grafts," and describes this as "rather promising." (A505; A499; A324.)

Surgeons had also devised a better way of anchoring the cannula so it remained in place during surgery. For example, a January 1995 prior art patent to Dr. Paul McAfee, who was NuVasive's expert in these proceedings, disclosed a cannula "anchored by means of sharp prongs or serrated teeth into a spinal bone or vertebrae," and also showed that this end was threaded and could be screwed into (or

out of) the rest of the cannula. (A537-45 at A539, A542-43 at 3:37-41, 6:1-18; A321.) Figure 2 of the prior art McAfee patent shows this cannula, while Figure 5 shows the end portion with the teeth detached from the rest.

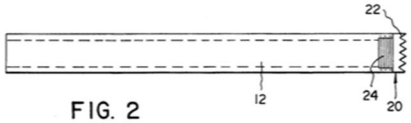


FIG. 2

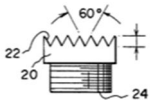


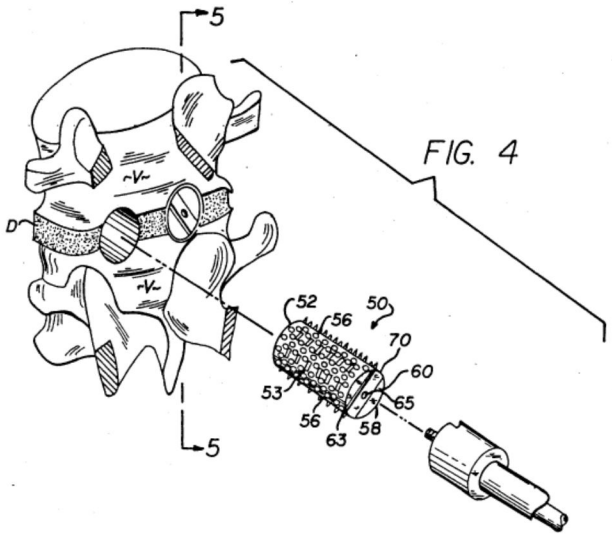
FIG. 5

Making this part of the cannula removable gave surgeons more flexibility—they could pick an end with appropriately sized teeth (or none at all), depending on the specifics of the patient and the surgical site. (A321-22.) Surgeons also knew the using longer teeth could be advantageous because they more readily penetrated into the spinal site and were thus more firmly "seated" there. (A323; A523; A533 at 9:22-30.) Other prior art, like the Michelson '247 patent discussed below, had these same features. (A322-23; A523; A533 at 9:22-25.)

A third issue was the shape and size of the implant used. In a spinal fusion surgery, all or part of the irritated disc is removed, and the issue then becomes what, if anything, should be put in its place. Surgeons initially used bone implants for many years, but then started using artificial implants in the early 1980s, such as the prior art artificial cylindrical fusion basket implant invented by Dr. George Bagby and disclosed in U.S. Patent 4,501,269. (A324.) Another implant designed that followed years later was disclosed in the prior art U.S. Patent 5,015,247 to Dr. Gary Michelson, the

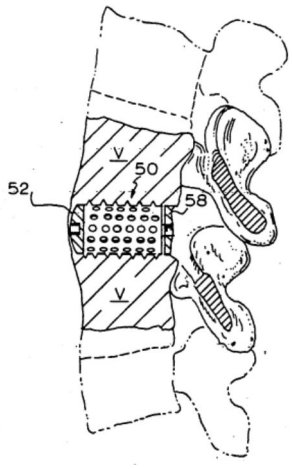
inventor of the patent-in-suit. (A522-36.) The '247 patent observed that there were some existing surgeries where "nothing is placed into the space left" after removal of a damaged disc. (A529 at 1:17-22.) This was a problem because "[p]lacing nothing in the space allows the space to collapse, which may result in damages to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation." (*Id.*) The '247 patent addresses this with an implant that "is space occupying within the disc space," and had several other supposedly helpful characteristics. (*Id.* at 1:8-16.)

The prior art Michelson '247 patent proposed inserting a pair of long, threaded cylindrical implants into a drilled borehole in the disc and portions of the adjacent vertebrae from the patient's back (posterior), as shown in Figure 4 below.



(A528; A325.) Each implant would span nearly the full length from the patient's front to back, as shown in Figure 5, which is a side view of the patient (and thus posterior insertion would be from the right side). (A528; A325-27.)

FIG. 5



The prior art '247 implants prevented vertebral collapse because they were larger from front to back than earlier implants (giving them more surface area), and, when used as a pair and placed toward the stronger cortical bone near the rim of the vertebrae, occupied more of the disc space from side-to-side. The '247 patent explains that, as a result, its implants better held the load of the vertebrae above them than smaller prior art implants that had been placed in the center of the disc space:

> The collapse of the interspace—While both the present invention and the [prior art] BAGBY device can be fabricated to withstand the compression forces within the interspace, the interspace may nevertheless collapse under the superincumbent body weight as the implant settles into the vertebral bone. This is related to the load per unit area. Again, the present invention is superior to the BAGBY device in at least four ways. First, ***the present invention offers considerably greater surface area to distribute the load***. Second, while the BAGBY device is placed centrally, ***the present device is placed bilaterally where the bone tends to be more cortical and much stronger out towards the rim***. . . .

(A530-31 at 4:63-5:7.)

The prior art Michelson '247 patent acknowledged there were anatomical constraints on how long its implant could be when inserted from the back. The spinal

cord runs along the patient's back, so the implant had to be slightly shorter than the full depth of the vertebrae to prevent any chance of contact. (A533 at 9:39-46, 10:30-36.) The patent thus describes an example in which the surgeon inserts a 26 mm implant into an opening created by a 28 mm drill bit, which "virtually guarantees that the implant 50 will be recessed into the vertebral bodies more than 2 millimeters and cannot protrude into the spinal canal." (A533 at 10:30-36.) In Figure 5, the spinal canal would be located behind the implant (to the right in the Figure), and thus the implant 50 is recessed 2 millimeters so that it does not interfere with nerves in the spinal canal behind it. But this implant occupied over 90% of the opening from front to back (substantially the full distance), and, if inserted laterally, there would have been no need to shorten it to avoid contacting the spinal cord. (A2794-95.)

Others also recognized the advantages of a long, lateral implant that covered substantially the full length of the vertebrae and seated on the hard cortical bone near the rim. A prior art patent to Dr. John Brantigan filed in 1991 disclosed oval implants that were "bottomed on the hard bone faces or end plates of adjacent vertebrae," shaped "to conform with the general outline perimeter of the vertebrae," (A507-16 at A511 at 2:1-5), and "dimensionally similar to normal vertebral bodies." (A507.)

II. The '997 Patent: Dr. Michelson Attempts to Claim Modifying Posterior Implants for Use in a Lateral Procedure With Prior Art Tools.

Warsaw's patent-in-suit—U.S. Patent 8,251,997—is the latest in a long line of related patents to Dr. Michelson. (A81-117.) The '997 patent claims priority to an

earlier February 1995 application that issued as U.S. Patent 5,772,661. (A81.) Both share a common specification and discuss surgical methods "by a lateral or an anterolateral surgical approach," rather than a posterior approach like the prior Michelson '247 patent. (A103 at 3:34-42; A105 at 7:64-8:15; A111 at 20:27-54.) Nevertheless, the '661 patent claimed priority to Michelson '247. (A546.) The '997 patent does not, probably because that would have eliminated any patent term.

Given the close relationship among these patents, it is perhaps no surprise that Michelson '997 describes using the same type of cylindrical, threaded implant used in the '247 patent. (*Compare* A100, *with* A528.) The '997 patent acknowledges this similarity by explaining that the same type of cylindrical, threaded implant can be used for procedures where the implant is put in from the patient's side or from front-to-back, as long as its length is appropriately modified based on basic human anatomy:

> Further, as the lumbar vertebrae and discs are much wider from side to side then they are deep from front to back, it can be appreciated that when single implants of the same diameter are inserted across a given lumbar disc, the ***laterally inserted implant I may be of a much greater length and thus have more area of contact, for stability and fusion than implant 1090 inserted from anterior to posterior***.

(A111 at 21:4-11.) So, as in the prior Michelson '247 patent, the '997 implant is lengthened to increase surface area for contact with the vertebrae and the stronger bone near the rim, thus increasing stability. The '997 patent's figures illustrate how the single, longer '997 lateral implant (Fig. 30) compares to a pair of prior art cylindrical implants like those in the prior Michelson '247 patent (Fig. 32). (A100.)

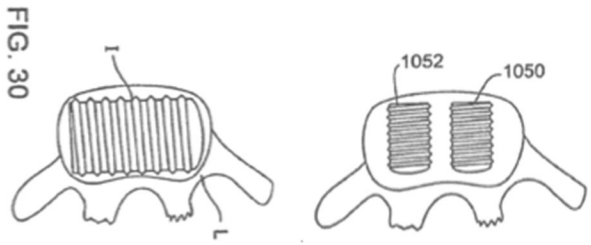


FIG. 32

Although the length of '997 implant is important, the specification uniformly depicts it as occupying less than the full transverse width of the vertebrae. For example, Figure 23 shows the cylindrical implant after lateral insertion, as viewed from the patient's front. (A98; A105 at 7:34-39.) The annotated version below shows the '997 implant does not span the full width of the vertebrae:

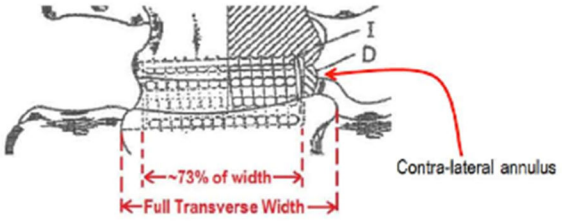
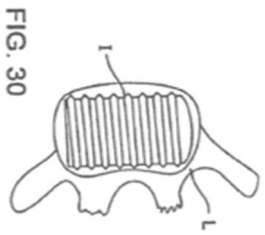


FIG. 23

(A313-14.) The fact that Figure 23 shows the contra-lateral annulus structure (to the right of the leading edge of the implant I) is still in place is a tell-tale sign that the '997 implant doesn't span the full transverse width—it would be impossible for the implant to span the full transverse width without removing the contra-lateral annulus. (*Id.*) Likewise, Figure 30 confirms that the '997 implant does not actually span the full transverse width, as it shows a top view after lateral insertion, and there is space (white) between the ends of the implant and the perimeter of the vertebral body:



(A100; A315-16.)

Most of the '997 patent claims require lateral insertion of an implant "being sized to occupy ***substantially*** the full transverse width of the vertebral bodies" using prior art tools. Claim 9 is representative and excerpts are shown below. A key dispute for NuVasive's appeal involves the limitation on the implant's length, but we reproduce other parts of the claim for context:

9. A method comprising:

> making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine … said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;
>
> advancing a first surgical instrument having a length into the body of the patient through said incision…
>
> advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument…
>
> advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument…
>
> positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space…

> inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and
>
> inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine…
>
> ***the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae***. . . .

(A113 at 23:60-24:64.) The dependent claims (10-16) add no further limitations of substance, and merely recite further known prior art tools, like using the implant with a plate to further stabilize the spine. (A113-14 at 24:65-25:17; A327-28; A517-21.)

Another set of the '997 claims, however, recites lateral insertion of an implant "being sized to occupy the ***full*** transverse width of the vertebral bodies" using prior art tools. Independent claim 24 is representative of this set:

> 24. A method comprising:
>
> making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine … each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space…
>
> [similar limitations to claim 9 relating to the three surgical instruments]
>
> inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine…

> ***the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae****.…*

(A114-15 at 26:43-28:20.) Again, the dependent claims (25-30) recite the same known, prior art features as claims 10-16. (A115 at 28:21-37; A337-38; A517-21.)

The Patent Office had previously identified a priority problem with claims similar to claims 24-30, a problem that, as discussed below, is relevant to some of NuVasive's proposed grounds for *inter partes* review. During reissue proceedings on the parent '661 patent, Warsaw amended those claims to require "positioning said implant to contact at least a portion of a cortical rim of at least one of the adjacent vertebrae with each of said ends of said implant." (A284.) The rim is on the edge of the vertebrae, so an implant that contacted the rim would span the full transverse width, as in claim 24 of the '997 patent. The Patent Office rejected the proposed '661 claims as improperly adding new matter, refusing to accept Warsaw's argument that Figure 30 discloses such an implant. (*Id.*) So Warsaw abandoned the '661 reissue and instead pursued the '997 patent claims in a continuation before a different examiner.

III. The *Inter Partes* Review Proceedings.

A. The Board Institutes Review on Most of the Requested Grounds, But Finds The Grounds Based on Intervening Art Redundant.

NuVasive filed two petitions for *inter partes* review that presented multiple grounds on which each claim of the '997 patent is invalid. (A238-302; A4860-4920.) One petition related to claims 1-8, while the other related to claims 9-30.

NuVasive presented two alternative sets of invalidity grounds, depending on which priority date the Board decided was appropriate for the '997 claims. If the Board decided that the claims were entitled to the 1995 priority that Warsaw sought, then NuVasive showed the claims were invalid based on the Jacobson and Leu prior art, either Brantigan, McAfee, or Michelson '247, and, for some dependent claims, the Frey patent. (A248-82.) But, if the Board instead adhered the '661 examiner's position that these types of claims were not entitled to a 1995 priority date, then, at most, they would only be entitled the 2011 priority date of the '997 application. NuVasive thus presented alternate grounds based on different, intervening prior art. (A282-301.) These intervening references—such as the Lynn patent—explicitly disclosed lateral implants that spanned the full transverse width. (A299-300; A613 at 15:59-61 (describing an implant "sized to generally span across the entire width of the adjacent vertebral members"); *see also* A588, A599-600, A605 (figures showing same).)

The Board granted *inter partes* review on each claim, relying only on NuVasive's grounds based on the earlier, pre-1995 prior art. (A949-72; A5792-5811). The Board found that the pre-1995 prior art suggested, among other things, the claimed implant length. (A965-69.) The Board thus found that NuVasive's grounds on the post-1995 references were redundant, and declined to address them further. (A969-70.)

B. The Board Takes Inconsistent Positions, Invalidating Some Claims, But Not Others.

The Board subsequently rendered final written decisions in which it invalidated claims 1-8 and 17-23 as obvious, but not claims 9-16 and 24-30. (A1-37; A45-80.)

When invalidating the first two sets of Warsaw's claims, the Board rejected Warsaw's arguments about the prior art's disclosures and combinability. (A7-25.) It found that Jacobson disclosed a "true" direct lateral procedure, (A7-16), that Brantigan disclosed an "implant being sized to occupy substantially the full transverse width of the vertebral bodies," (A16-21), and that the skilled artisan would have combined these teachings with Leu's sequential dilators and Frey's fixation plate to arrive at the claimed invention. (A21-25.) The Board also rejected Warsaw's alleged secondary criteria, finding no nexus between the claims and any alleged commercial success or industry praise, and no evidence of copying. (A25-31.)

With respect to the other claims, however, the Board conducted a more rigid analysis. Despite having found the claimed implant's length was present in the Brantigan prior art, it now found this limitation was missing from the prior art combinations asserted against claims 9-16 and 24-30 because NuVasive was primarily relying on Michelson '247 for that limitation with respect to these claims. (A31-33.) The Board looked not to whether a skilled artisan familiar with Michelson '247 would have thought the limitation obvious. Instead, it focused narrowly on whether the Michelson '247 patent itself—a patent relating to a posterior approach rather than a

lateral (transverse) approach—expressly taught or suggested an "implant being sized to occupy substantially the full transverse width of the vertebral bodies." (A31-33.)

The Board declined to invalidate claims 9-16 and 24-30 because it found no such express teaching or suggestion. Agreeing with Warsaw, the Board stressed that "there is ***nothing in the written disclosure*** of Michelson '247 that teaches a surgeon to size an implant to span as much of the length as possible from an anterior to posterior direction." (A33.) The Board did not address Michelson '247's Figure 5 at all, much less its emphasis on increasing the implant's surface area (and thus length) and on placing the implant out toward the stronger bone at the rim of the vertebrae to prevent collapse. The Board acknowledged that Michelson '247 taught inserting a 26 mm implant into a 28 mm opening, but thought that it "does not disclose the length of the implant (or opening) in relation to the size of the vertebral body," (A32), even though this is shown in Figure 5. (A32.) The Board also observed that Michelson '247, "does not appear to disclose elongating the drill to a length greater than 28 mm," (*id.*), but not whether the skilled artisan would do this if the implant was inserted laterally where there was no concern of it contacting the spinal cord.

The Board's findings on Michelson '247 were the opposite of what it believed in its institution decision, where it had agreed with NuVasive's argument that "Michelson '247 further suggests that an implant 'should extend longitudinally across the full disc space along the direction of insertion.'" (A965.) Nevertheless, the Board did not consider whether its change of heart would require rethinking its earlier

conclusion that the other grounds for invalidating these claims, which included the Lynn reference, were still redundant.

C. The Board's Denial of Rehearing.

On rehearing, the Board repeated the legal errors it made previously. (A38-44.) It first focused on what Michelson '247 expressly taught, rather than what would have been obvious to the skilled artisan based on the prior art as a whole. For example, it criticized NuVasive's reliance on the part of Michelson '247 teaching the advantages of an implant with greater surface area (and thus greater length) that was placed toward the stronger cortical bone on the vertebral rim because "Petitioner does not show sufficiently that Michelson '247 also discloses that the implant is sized to occupy substantially the full transverse width of the vertebral bodies." (A40.) The Board rejected NuVasive's arguments about other parts of the Michelson '247 patent in the same way, finding that the Michelson '247 did not select a 26 mm implant "in order to be sized to occupy substantially the full transverse width." (*Id.*) The Board also found that "Petitioner does not explain sufficiently how this feature would have been obvious to one of ordinary skill in the art in view of the lack of such a suggestion in any of the cited references," (A41), even though it had found, on the other claims, that the Brantigan '327 patent ***did*** suggest this feature, (A16-21), and even though NuVasive's expert had explained that the skilled artisan would have predictably picked a longer implant to prevent the vertebrae from collapsing. (A326-27.)

This appeal followed.

SUMMARY OF THE ARGUMENT

The Board legally erred by basing its decision solely on its belief that Michelson '247, which relates to posterior implants, did not expressly disclose or suggest a long lateral implant. *KSR* precludes so rigid and formalistic an analysis. The Board should have asked whether a skilled artisan, based on his knowledge of all the prior art and his ordinary creativity, would have selected the claimed implant. NuVasive's evidence showed he would have because such an implant would increase stability and prevent vertebral collapse by occupying more of the disc space and resting on the stronger, cortical bone on the rim. The Board further erred by ignoring its own finding that the prior Brantigan '327 patent ***did*** disclose the same length in claims 9-16.

The Board also erred factually because Michelson '247 ***does*** suggest an implant of the claimed length. Figure 5 shows an implant that spans substantially the full vertebral depth, and the accompanying description stresses that the implant's greater surface area (which is due to its greater length) and its placement toward the rim of the vertebrae increases stability and prevents collapse. The skilled artisan would apply that to a lateral implant by selecting one that spans the full transverse width, especially because there would be no risk of contacting the spinal cord or aorta.

Alternatively, this Court should remand for the Board to consider the grounds it deemed redundant based on its initial view that Michelson '247 taught the claimed length. When the Board changed its mind in the final written decision, NuVasive's alternative grounds were no longer redundant, and they should have been addressed.

LEGAL STANDARDS

Obviousness is a question of law that depends on underlying facts, *i.e.*, the scope and content of the prior art, differences between the prior art and the claimed invention, the level of ordinary skill, and any secondary indicia. *Randall Mfg. v. Rea,* 733 F.3d 1355, 1362 (Fed. Cir. 2013). This Court reviews the Board's ultimate legal determination *de novo* and its factual findings for substantial evidence. *Id.*

The ground rules for a proper legal analysis of obviousness are familiar, but worth repeating. "The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). Moreover, "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *Id.* at 421.

Indeed, obviousness do not turn "on whether an invention is equivalent to some element in the prior art but rather whether the difference between the prior art and the subject matter in question is a difference sufficient to render the claimed subject matter unobvious to one skilled in the applicable art." *Dann v. Johnston*, 425 U.S. 219, 228 (1976). Thus, "the mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Id.* at 229-30.

ARGUMENT

I. The Court Should Reverse the Board's Decision on Claims 9-16.

A. The Board Legally Erred By Applying a Rigid Analysis That Was Improperly Limited to the Express Disclosures of Michelson '247.

The obviousness issue on claims 9-16 is a narrow one, given the Board's findings on the prior art made in conjunction with the other claims. The Board found that the skilled artisan would have performed a lateral spinal fusion surgery by combining the methodology and tools (e.g., sequential dilators and fixation plates) taught in Jacobson, Leu, and Frey. (A7-25.) The main remaining question, then, is whether it would have been obvious for the skilled artisan to use an implant with a length sized "to occupy substantially the full transverse width of the vertebral bodies" between which it was inserted. The Board also made a finding on this issue when invalidating claims 1-8 and 17-23. It held that using such an implant in a lateral spinal fusion would have been obvious based on the Brantigan '327 prior art patent. (A16-21, A23-25, A59-64, A66-68.) But the Board failed to consider that same finding when addressing claims 9-16, and instead narrowly focused on whether Michelson '247 expressly disclosed or suggested an implant with that size. That rigid aspect of the Board's legal analysis was error for at least two reasons.

First, the Board should not have confined its legal analysis to what Michelson '247 expressly disclosed or suggested with respect to posterior implants. Instead, it should have asked whether the skilled artisan familiar with Michelson '247—along

with the rest of the prior art—would have applied his knowledge and creativity to chose a lateral implant with the claimed length. This Court recently reminded the Board not to use the kind of rigid approach it did here:

> In *KSR,* the Supreme Court criticized a rigid approach to determining obviousness based on the disclosures of individual prior-art references, with little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications. Rejecting a blinkered focus on individual documents, the Court required an analysis that reads the prior art in context, taking account of "demands known to the design community," "the background knowledge possessed by a person having ordinary skill in the art," and "the inferences and creative steps that a person of ordinary skill in the art would employ."

Randall, 733 F.3d at 1362 (internal cites omitted). This Court thus rejected the Board's analysis where it narrowly focused on the four corners of a specific combination of references, rather than considering all the evidence about the creativity and ingenuity the skilled artisan would have applied:

> The Board's analysis in this case ran afoul of that basic mandate. By narrowly focusing on the four prior-art references cited by the Examiner and ignoring the additional record evidence Randall cited to demonstrate the knowledge and perspective of one of ordinary skill in the art, the Board failed to account for critical background information that could easily explain why an ordinarily skilled artisan would have been motivated to combine or modify the cited references to arrive at the claimed inventions.

Id.

In doing so, this Court was simply restating long-established legal principles: asking whether the prior art expressly discloses particular limitations or modifications "is not the proper approach to the issue, which is whether the hypothetical person of

ordinary skill in the art, *familiar* with all that [the prior art references] disclose, would have found it obvious" to arrive at the claimed invention. *In re Sovish*, 769 F.2d 738, 742 (Fed. Cir. 1985) (emphasis in original). As a result, the skilled artisan's background knowledge and creativity must always be part of the analysis. *See, e.g., In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (rejecting an argument about a reference's failure to expressly disclose a limitation because the reference "must be considered together with the knowledge of one of ordinary skill in the pertinent art").

The Board thus erred here because it stopped at asking whether Michelson '247 expressly disclosed or suggested an implant with a length "sized to occupy substantially the full transverse width." (A31-33; A39-43.) The Board seemed to assume that anything less than a sentence in Michelson '247 that said "if you are going to take this posterior implant and use it in a lateral spinal surgery, then make it longer, and, in particular make it long enough to occupy the whole transverse width of the vertebrae" would be legally insufficient. That is not the right standard.

The Board should have instead asked whether a skilled artisan familiar with Michelson '247 who was contemplating performing a lateral fusion surgery would have applied his ordinary creativity to select an implant with that length. NuVasive submitted expert testimony that a skilled artisan ***would*** have done so. (A325-27.) NuVasive's Dr. McAfee opined that the skilled artisan, based on his experience and knowledge would have predictably selected an implant that spans across the full disc

space to provide improved support and to prevent the vertebrae from collapsing after the disc is removed:

> ***Based on my knowledge and experience in this field*** and my review of Jacobson, Leu, McAfee, and Michelson '247, I believe that a person of ordinary skill in the art at the time (at least as early as 1992) would have been prompted to use a longer threaded fusion implant (as suggested by Michelson '247) for use in Jacobson's lateral insertion path ***so that the implant extends longitudinally across the full disc space in the lateral insertion direction and advantageously provides the improved mechanical support and reduces the likelihood of the implant collapsing into the soft cancellous bone in the central region of the vertebrae***. In the resulting surgical method … the fusion implant would be inserted into the disc space via a lateral approach, so the ***relative dimensions of Michelson's '247 implant 50 would have been predictably selected in accordance with the lateral insertion orientation*** to provide a length of the implant that is "sized to occupy substantially the full transverse width of the vertebral bodies" and that is "greater than the depth of the disc space."

(A326-27 (emphasis ours).) The skilled artisan would have known these things both from Michelson '247—which stressed that longer implants with greater contact area placed at the stronger bone at the edges of the vertebrae provided more stability—but also from his own knowledge that longer implants have more contact area, and that the spine is wider than it is deep, meaning that implants put in from the side can be longer without contacting and damaging any vital organs. Indeed, the '997 patent itself acknowledges as much because it says that it "can be appreciated" by the skilled artisan that a laterally inserted implant "may be of a much greater length and thus have more area of contract, for stability and fusion than implant 1090 inserted from anterior to posterior." (A112 at 21:4-11.) So the '997 inventor simply modified his own prior posterior implant in a predictable way that was consistent with human

anatomy to meet a need known by skilled artisan (and reported in Michelson '247)—i.*e.,* the need for the vertebrae to remain stable and not collapse. (A530-31 at 4:63-5:7.) The Board legally erred by failing to consider whether selecting an implant with the claimed length would have been obvious to the skilled artisan based on these design needs and the skilled artisan's knowledge and creativity.

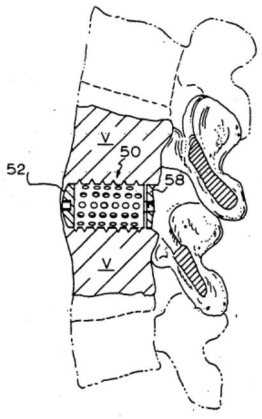
Second, the Board should have considered the impact of its finding that the Brantigan '327 prior art expressly disclosed an implant with a length spanning substantially the full transverse width on the validity of claims 9-16. When addressing now-invalidated claims 17-23, NuVasive's Dr. McAfee explained the skilled artisan would have understood Brantigan '327 to disclose this limitation and have employed to "provide the predictable result of reducing the chances of the implant collapsing into the soft cancellous bone in the central region of the vertebrae." (A331-32.) The Board agreed when invalidating those claims. (A16-21.) It was a triumph of rigidity and formalism for the Board not to consider that very same finding when analyzing claims 9-16, which have the exact same limitation. After all, the Brantigan '327 patent would have been part of the skilled artisan's general knowledge at the relevant time (i.e., the scope and content of the prior art), so it was highly relevant to the obviousness of claims 9-16, regardless of whether it was part of the specific combination of references that the Board was considering whether to apply to those claims. *Randall*, 733 F.3d at 1362. Indeed, if there were any question about whether the skilled artisan would have selected an implant spanning the full transverse width,

then Brantigan '327 answered it, because it ***did*** disclose such an implant. Yet the Board ignored Brantigan '327 when analyzing the validity of claims 9-16. *KSR* forbids so narrow an analysis.

B. The Board Wrongly Found Michelson '247 Did Not Suggest an Implant Extending Substantially the Full Direction of Insertion.

The Board's legal errors were compounded by a factual one—the prior art Michelson '247 patent *does* expressly teach the skilled artisan to use an implant should span substantially the full dimension of the disc space in the direction of insertion. Figure 5 of the Michelson '247 patent is crystal clear. It shows a cylindrical implant inserted from the patient's back spanning substantially the full depth of the vertebrae, with a slight recess at the back to prevent contact with the spinal cord. (A528.)

FIG. 5



Moreover, the Michelson '247 example of a 26 mm implant inserted into a 28 mm opening teaches the same thing—the implant occupies over 90% of the opening. (A533 at 10:31-36.) The '247 patent explains why the implant has these dimensions—its greater length results in an implant of greater surface area that provides greater stability to prevent the vertebrae from collapsing after a disc is removed. (A529-31 at

1:8-31, 4:63-5:16.) Moreover, Michelson '247 teaches using a pair of implants positioned on the stronger bone at the edge of the vertebrae, underscoring the need to occupy as much of the disc space as possible to prevent collapse. (*Id.*)

The Board's responses to these points were insufficient. The Board did not mention Figure 5 at all in its initial opinion, and, on rehearing, it noted only that patent figures "do not define the precise proportions of the elements" and might not be drawn to scale. (A40-41.) But the issue here is not whether the prior art discloses any precise or exact size. The '997 patent itself does not disclose or claim anything precise—claims 9-16 require only an implant "sized to occupy ***substantially*** the full transverse width" of the vertebrae. The issue is whether the prior art discloses an implant with dimensions comparable to what is claimed. It does. The Michelson '247 prior art (left) shows an implant spanning at least as far from front to back as the Michelson '997 patent (right) shows the claimed implant spanning from side-to-side.

PRIOR ART **MICHELSON '997**

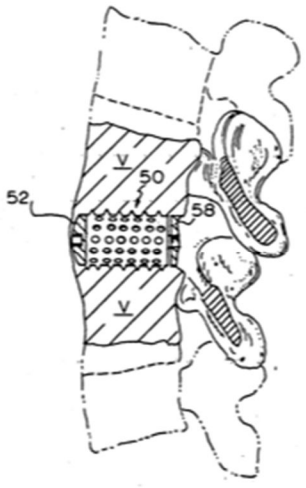


FIG. 5

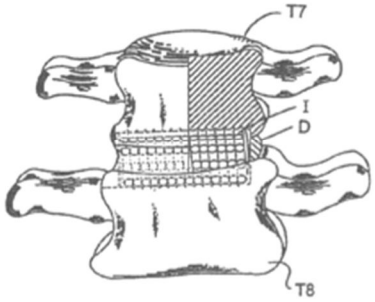


FIG. 23

The prior art thus describes using an implant that spans substantially the dimension of the disc space just as clearly as the patent-in-suit. That is especially true given that the Board was required to give the '997 claims their broadest reasonable construction. *See In re Cuozzo Speed Techs.,* 2015 WL 448667, at *5-8 (Fed. Cir. Feb. 4, 2015). Under such a construction, any doubts about whether the prior Michelson '247 implant spanned "substantially" the full dimension of insertion fall away.

The Board's concern that Michelson '247 did not specify how the exemplary 26 mm implant related to vertebral sizes was likewise unfounded. It was undisputed that the skilled artisan knew the dimensions of the average person's vertebrae, (*see, e.g.,* A390-91), and Warsaw itself argued the relevant vertebrae were 31-35 mm deep. Even accepting that as true, the implant would still span from 74-83% of the vertebrae, which is greater than the 73% of the disc space that Figure 23 of the '997 patent shows the claimed implant occupying. (A313-14.) The term "substantially the full transverse width" must be given its broadest reasonable construction during *inter partes* review proceedings, and Warsaw cited nothing in the '997 patent specification to suggest that construction would exclude an implant spanning 83% of the transverse width. If it did, it would pose a serious new matter problem, which is why NuVasive presented its alternative ground of rejection based on the intervening Lynn patent.

Finally, the Board was wrong to dismiss the teachings in Michelson '247 to select a long implant with a greater surface area to increase stability and prevent collapse of the vertebrae. The Board's initial opinion was again silent on this

evidence, but, on rehearing, it dismissed this passage as disclosing "a device with greater surface area than the [prior art] 'BAGBY device' and that the device is placed bilaterally." (A40.) But the reason the device has greater surface area is because it is longer—so long, in fact, that, as shown in Figure 5, it occupies substantially the entire depth of the vertebrae. Likewise, the fact the Michelson '247 implant is placed bilaterally toward the edges of the vertebrae (on the cortical bone) further suggests that the skilled artisan who wanted to insert the same type of implant laterally would select one with a length that spanned substantially the full transverse width of the vertebrae. (A326-27.) Both arrangements would provide maximum support and stability to prevent the vertebrae from collapsing. (*Id.*)

C. Claims 9-16 Would Have Been Obvious to the Skilled Artisan Under the Correct Analysis.

When the Board's legal and factual errors are corrected, claims 9-16 are obvious as a matter of law. The Board already made factual findings that the skilled artisan would have combined the prior art Jacobson, Leu, and Frey references to arrive at a lateral spinal fusion surgery using three sequential dilators, (A7-16, A21-25), and the analysis above demonstrates the skilled artisan would have selected an implant with the claimed length. (A324-27.) The only additional limitation in claims 9-16 not present in the invalidated claims is that the third dilator have a "removably attached" end portion with prongs to anchor it to the vertebrae so it does not move while the surgeon works. (A114 at 25:52-64.) Both the McAfee and Michelson '247 references

taught this limitation, (A321-23; A539, A542-43 at 3:37-41, 6:1-18; A523; A533 at 9:22-26), and the skilled artisan would have combined it with the others because it gave the option of selecting an end that was the right size for a particular patient or part of the spinal column. (*Id.*) Warsaw did not seriously rely on this limitation to distinguish prior art—it devoted only two conclusory paragraphs of its briefing to the issue. (A1212-13.) This Court should thus hold claims 9-16 obvious as a matter of law. At a minimum, it should vacate and remand with instructions for the Board to reconsider the obviousness of these claims using the correct legal analysis and facts.

II. The Court Should Reverse the Board's Decision on Claims 24-30.

The Board's decision on claims 24-30 should be reversed for many of the same reasons as those given for claims 9-16. The only difference is that claims 24-30 recite an implant that is "sized to occupy the ***full*** transverse width of the vertebrae," rather than substantially the full transverse width. This only minimally impacts the analysis.

The Board made a similar legal error when addressing claims 24-30 to one of the errors it made on claims 9-16. The Board again asked whether Michelson '247 expressly disclosed or expressly suggested an implant "sized to occupy the full transverse width," (A31-33), rather than asking whether the skilled artisan would have used his background knowledge, familiarity with Michelson '247, and creativity to select an implant of this length. But again, NuVasive submitted expert evidence from Dr. McAfee, in which he opined the skilled artisan—based on his general knowledge and experience in addition to Michelson '247—would have been prompted to use a

longer implant that spanned "across the full disc space" and contacted the stronger cortical bone on the edges to advantageously increase stability and prevent vertebral collapse. (A336-37.) The Board never discussed this evidence, and, by confining its analysis to the express disclosure of Michelson '247, it committed legal error.

The Board's factual errors about the Michelson '247 disclosure when comparing it to claims 9-16 also infected its analysis of claims 24-30. The Board's opinions treated the two sets of claims together, and it applied its same factual mistakes about Michelson '247 to both sets of claims. (A32-33; A42.) Therefore, if the Board finds any factual error, it applies equally to both sets of claims and requires reversal on both sets.

When these legal and factual errors are corrected, claims 24-30 are invalid as obvious for the same reasons as claims 9-16. As explained above, the Board already found that the skilled artisan would have combined the prior art Jacobson, Leu, and Frey references to arrive at a lateral spinal fusion surgery using three sequential dilators, (A7-16, A21-25), and the analysis above demonstrates the skilled artisan would selected an implant with the claimed length. (A333-37.) The only additional limitation in claims 24-30 not present in the others is that the third dilator have three elongated portions to anchor it to the vertebrae. (A115 at 27:9-30.) The Michelson '247 reference taught this limitation, (A276-78, A523; A333-35), and the skilled artisan would have combined it with the others to more firmly seat the instrument in the disc space. (*Id.*) Again, Warsaw did not seriously rely on this limitation to distinguish

prior art—it devoted one short paragraph of briefing to it. (A1213.) As with claims 9-16, this Court should thus hold claims 24-30 obvious as a matter of law. At a minimum, it should vacate and remand with instructions for the Board to reconsider the obviousness of these claims using the correct law and facts.

III. Alternatively, the Court Should Vacate and Remand with Instructions for the Board to Consider the Grounds It Deemed Redundant.

A. The Board's Final Written Decision Should Have Considered NuVasive's Other Grounds Because They Were No Longer Redundant.

The final decision confirming claims 9-16 and 24-30 should not stand in any event because the Board never ruled on two of NuVasive's invalidity grounds. NuVasive's presented two alternative sets of grounds—one set based on a 1995 priority date, and the other set based on a 2011 priority date. (A238-302.) The Board instituted review on the first set of grounds, and thus decided the second set were "redundant in light of the grounds on the basis of which we institute review." (A969-70.) In particular, the Board had instituted review on the first set of grounds because it thought the skilled artisan would have combined the prior art, including Michelson '247, to arrive at an implant that spanned substantially the full transverse width of the vertebrae, or (in the case of claim 24) the full transverse width:

> [O]ne of ordinary skill in the art, based on Jacobson, would have accessed the intervertebral space laterally to insert an implant, and would have further utilized an implant of a length that occupied substantially the dimension of the intervertebral space in the direction of insertion based on Michelson '247.

(A965-66; *see also* A969.) But then, in its final written decision, the Board changed its mind and found that Michelson '247 did not sufficiently disclose this limitation. (A31-33.) The Board is certainly allowed to rethink its initial views (although, in this case, it made the errors identified above when it did so). When it does so, however, the Board should also be required revisit the other parts of its initial analysis that might be impacted by its changed position.

The Board legally erred by failing to do that here. The Board's reinterpretation of Michelson '247 in the final written decision necessarily impacted its redundancy determination. Having determined claims 9-16 and 24-30 were not invalid based on NuVasive's grounds involving Michelson '247 because of the "substantially the full" or the "full transverse width" claim limitation, the alternative grounds could no longer be redundant because they involved a reference that expressly disclosed these limitations. (A299-300.) In particular, the Lynn patent expressly taught a lateral implant "sized to generally span across the entire width of the adjacent vertebral members." (A613 at 15:59-61; *see also* A588, A599-600, A605 (figures showing same).) So, if the Board now thought this limitation was missing from Michelson '247, it should have actually addressed the priority date issue on the merits. And, if it reached the same conclusion as the '661 reissue examiner and found the claims not entitled to a 1995 priority date, it should have invalidated the claims based on these alternate grounds. NuVasive expressly asked the Board to consider the "redundant" grounds with respect to claims 24-30 if it changed its mind about Michelson '247. (A1689.)

The Board's final written decision never mentioned that argument. That was legal error.

An analogy may help illustrate the point. Suppose a defendant in district court raises both invalidity and noninfringement defenses; suppose further that the district court grants summary judgment of invalidity, and thus finds it unnecessary to decide noninfringement. That is the district court's prerogative—it can manage its docket and chose not to reach alternative arguments it may never need to consider. But if the invalidity judgment is later reversed, either on reconsideration in the district court or on appeal, then the district court has to consider the remaining arguments. They are no longer unnecessary to decide. The same is true here. Although, it may have been unnecessary to consider the "redundant" grounds initially, it became necessary after the Board changed its mind about the Michelson '247 patent. Therefore, if this Court does not outright reverse the judgment and find claims 9-16 and 24-30 invalid, it should, at a minimum, send the case back to the Board for it to consider the grounds it has never reached.

B. This Court Has Jurisdiction to Address the Board's Failure to Address All NuVasive's Proposed Grounds of Invalidity.

For completeness, we note that this Court has jurisdiction to correct the Board's error because it was part of the Board's final written decision, which is appealable to this Court. *See* 35 U.S.C. §§ 319, 141(c). The final written decision found that NuVasive had not shown that claims 9-16 and 24-30 were unpatentable

but failed to consider whether it would have reached the opposite conclusion if it considered all of NuVasive's proposed grounds of invalidity. NuVasive is seeking review of this error in the Board's final written decision—it is not attacking the Board's institution decision itself. This Court can thus review this issue as it would any other error in the Board's final written decision.

We are mindful that *St. Jude Medical v. Volcano Corp.*, 749 F.3d 1373 (Fed. Cir. 2014), holds that this Court has no jurisdiction to consider the Board's denial of an *inter partes* review petition, but that case does not preclude review here. There, the Board had denied review because St. Jude failed to file its request within the one-year window permitted by 35 U.S.C. § 315(b), and this Court held that determination was unreviewable. *Id.* at 1375-77. This case is different for two reasons. First, as noted above, NuVasive is not challenging the Board's decision at the institution stage, but an error in the Board's final written decision—namely, the fact it made a finding NuVasive had failed to show obviousness of claims 9-16 and 24-30 without considering two of NuVasive's grounds. Second, unlike *St. Jude*, this case does not really involve a denial of NuVasive's petition for *inter partes* review because the Board never made a decision on two of NuVasive's grounds one way or the other. It did not deny review on the merits—*i.e.*, because NuVasive had not shown a substantial likelihood the claims were invalid based on those grounds. *See* 35 U.S.C. § 314(a). Nor did it deny review for some procedural reason—*i.e.*, that the petition was filed outside one-year deadline or did not name the real-party in interest. *See* 35 U.S.C.

§§ 312(a)(2), 315(b). Instead, all the Board really did was find it unnecessary to decide whether it could institute review on the two grounds or not. So its statement that it "denied" review was not the same kind of denial as the one at issue in *St. Jude*, and neither that case nor the statute block appeal of the issue here.

We are equally mindful that *In re Cuozzo*, 2015 WL 448667, extended *St. Jude* to conclude that this Court cannot review attacks on a grant of institution after a final written decision. *Id.* at *2-4. But, again, NuVasive is not attacking the Board's institution decision. The problem instead is that, when the Board's final written decision changed its prior interpretation of Michelson '247, the Board had to then consider any other potential grounds of patentability.

Nevertheless, even if this Court were to decide that the statute blocked a direct appeal of this issue, it should still resolve it by treating this part of NuVasive's brief as a petition for *mandamus*. *See In re Cuozzo, LLC*, 2015 WL 448667, at *2-4 & n.5; 16 Charles A. Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice and Procedure* § 3932.1 (3d ed. 2012). As *Cuozzo* explains, this Court has not yet addressed whether the statute bars a party from using *mandamus* to challenge an error that begins at the institution stage and continues to infect the final written decision. NuVasive submits that *mandamus* is appropriate here because this case meets all three prerequisites to issuing the writ—(1) "the party seeking issuance of the writ [must] have no other adequate means to attain the relief he desires," (2) the "right to issuance of the writ is clear and indisputable," and (3) "the writ is appropriate under the circumstances" in

the exercise of this Court's discretion. *Id.* (*quoting Cheney v. U.S. Dist. Court for the District of Columbia*, 542 U.S. 367, 380 (2004).

The first condition will be satisfied if this Court decides it cannot entertain a direct appeal on this issue. NuVasive would have no alternative avenue to challenge the Patent Office's refusal to revisit its redundancy determination. The second condition is present because there is a "clear and indisputable error" here. As discussed above, the Patent Office based its decision not to proceed with NuVasive's alternative grounds on a premise (that Michelson '247 taught the claimed implant length) that the Patent Office has since abandoned. The Patent Office has articulated no other legal or factual basis for not considering NuVasive's alternative grounds.

The third condition is met because the Patent Office's decision implicates significant due process concerns and has potentially serious collateral consequences. NuVasive may now be faced with a situation where it is estopped from ever raising its alternative grounds again, either in the parties' co-pending district court litigation or in a subsequent PTO proceeding. *See* 35 U.S.C. § 315(e). That is a fundamentally unfair result where NuVasive did everything it could to obtain review of those grounds, only for the Patent Office to never actually decide whether they were substantively strong enough to warrant *inter partes* review. The potential estoppel effect is particularly unwarranted because the "redundancy" doctrine appears nowhere in the patent statute. In fact, the statute requires the Patent Office to issue "a final written decision with respect to the patentability of any claim challenged by the petitioner." *See* 35

U.S.C. § 318(a). This statutory command requires the Patent Office to at least address, in some form, all arguments raised by a petitioner.

Therefore, if this Court does not find the claims invalid as a matter of law, it should, at a minimum, vacate and remand with instructions for the Board to consider NuVasive's unaddressed alternative grounds of invalidity in light of its new view of Michelson '247.

CONCLUSION

For the reasons above, the Court should thus reverse and determine that claims 9-16 and 24-30 are invalid as obvious, or, at a minimum, vacate and remand to the Board for further consideration of the issues under a correct legal analysis and considering all relevant evidence and potential grounds for rejection.

Dated: February 19, 2015

Respectfully submitted,

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ADDENDUM

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Paper 65
Date: July 10, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00206
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

NuVasive, Inc. ("Petitioner") filed a petition (Paper 5) ("Pet.") seeking *inter partes* review of claims 9–30 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, "the '997 patent") pursuant to 35 U.S.C. §§ 311–319.[1] On

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[1] We cite to Petitioner's Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997 B2, filed April 3, 2013. Paper 5.

September 23, 2013, the Board instituted an *inter partes* review of all claims on six grounds of unpatentability (Paper 17) ("Dec. on Inst.").

Subsequent to institution, Warsaw Orthopedic, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 32) ("PO Resp."), and Petitioner filed a Reply (Paper 43) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 53. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 59) ("Opp."), and Patent Owner filed a Reply (Paper 60) ("PO Reply"). An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 52) and Patent Owner (Paper 54).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 17–23 of the '997 patent are unpatentable, but has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of the '997 patent are unpatentable.

A. The '997 Patent (Ex. 1002)[2]

The '997 patent describes methods and instrumentation for performing surgery on the spine along its lateral aspect. Ex. 1002, 3:34–36; Figs. 1 and 2. Guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for distractor 100 that is placed over the guide pin and inserted into the disc space to distract the vertebrae. Ex. 1002, 8:52–53; 9:12–14; 10:10–12; Figs. 2–5. Extended outer sleeve 140 is placed over the distractor and inserted into the disc space. Ex. 1002, 10:22–25, Fig. 12.

[2] We refer to Ex. 1002 submitted by Petitioner and dated March 22, 2013.

A spinal implant I is introduced through the extended outer sleeve and installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

B. Illustrative Claim

Claim 9 is illustrative of the claimed subject matter of the '997 patent, and is reproduced as follows:

> 9. A method comprising:
>
> making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;
>
> advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;
>
> advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

C. Cited Prior Art

The pending grounds of unpatentabililty in this *inter partes* review are based on the following prior art:

Jacobson	US 4,545,374	Oct. 8, 1985	(Ex. 1004)
Brantigan	US 5,192,327	Mar. 9, 1993	(Ex. 1006)
Frey	US 4,917,704	Apr. 17, 1990	(Ex. 1007)
Michelson ’247	US 5,015,247	May 14, 1991	(Ex. 1008)
McAfee	US 5,569,290	Oct. 29, 1996	(Ex. 1009)

Hansjörg F. Leu and Adam Schreiber; *Percutaneous Fusion of the Lumbar Spine: A Promising Technique*, 6(3) SPINE: STATE OF THE ART REVIEWS 593 (Sept. 1992) (Ex. 1005, “Leu”).

D. Pending Grounds of Unpatentability

This *inter partes* review involves the following asserted grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Jacobson, Leu, McAfee, and Michelson ’247	§103	9 and 16
Jacobson, Leu, McAfee, Michelson ’247, and Frey	§103	10–15
Jacobson, Leu, and Brantigan	§103	17 and 23
Jacobson, Leu, Brantigan, and Frey	§103	18–22
Jacobson, Leu, and Michelson ’247	§ 103	24 and 30
Jacobson, Leu, Michelson ’247, and Frey	§ 103	25–29

E. Claim Interpretation

The parties appear to agree with the interpretation of various claim terms of the '997 patent as described in the Decision on Institution with additions or modifications as set forth below. We incorporate our previous analysis for the non-disputed claim terms.

1. "a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes" (claim 9)

Patent Owner argues that an "axis lying in a coronal plane" should be construed as an axis that is lying in "a plane at right angles to a sagittal plane." PO Resp. 11. Petitioner does not contest Patent Owner's assertion that one of ordinary skill in the art would understand that a "coronal plane" would be oriented "at right angles to a sagittal plane." Pet. Reply 1. Thus, no further construction of this term is necessary.

2. "elongated portion" (claim 9)

Patent Owner argues that the term "elongated portion" should be broadly, but reasonably, construed as a portion in which "its length is *substantially* greater than its width." PO Resp. 12. Petitioner argues that "elongated" should be construed as a portion having a length greater than its width. Pet. Reply 1–2. As Petitioner points out, claim 9, for example, recites the "length of said single elongated portion being greater than the width . . . of said single elongated portion." Patent Owner does not show persuasively that the claims recite a requirement that the length of the elongated portion is "substantially" greater than the width of the elongated portion or that the Specification discloses such a requirement. Patent Owner

also does not provide a persuasive rationale as to why one of ordinary skill in the art would have assumed that the length of the elongated portion is "substantially" greater than the width of the elongated portion in view of the absence of the disputed qualifier in the claims and Specification.

We construe the elongated portion as having a length that is greater than the width of the elongated portion.

II. ANALYSIS

A. Grounds Based at Least in Part on Jacobson, Leu, and Brantigan (Claims 17–23)

Claim 17 recites a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae. Patent Owner contends that a path having an axis lying in a coronal plane, as recited in claim 17, must be a path that is "a direct or true lateral path to the spine." PO Resp. 11. Petitioner concurs. Pet. Reply 1.

Jacobson – "lateral"

Jacobson discloses a procedure in which "a cannula is passed laterally through the body," a needle that "is inserted laterally through the patient's side" that "may act as a guide member . . . for instruments that create the percutaneous body channel," a speculum that "is laterally inserted through body tissue" and is "used to create the lateral cavity through body tissue into which the cannula will be inserted." Ex. 1004, 5:1–2, 5:27–28, 5:49–51, 5:40–42, 8:53–55. Jacobson also provides drawings of the approach to the intervertebral space. The drawings depict a lateral approach to the intervertebral space, consistent with the textual description. Ex. 1004, Figs. 1–6.

Patent Owner argues that while Jacobson discloses accessing a disc space from a "lateral" aspect, the term "lateral" "has any number of meanings, including anterolateral, posterolateral, direct lateral, and lateral to the midline of the vertebral bodies" and that, despite Jacobson's disclosure of a "lateral" approach, Jacobson actually "discloses a posterolateral – not a direct lateral – approach to the spine." PO Resp. 19 (citing Ex. 2039, 37:25 – 39:1).

Petitioner provides testimony of Dr. Robert E. Jacobson to demonstrate what one of ordinary skill in the art would have understood the term "lateral" to mean in the context of performing a spinal fusion procedure. Ex. 1030 ¶ 5. Dr. Jacobson testifies that one of ordinary skill in the art would not have used (or understood) the term "direct lateral" but, instead, would have used the term "lateral" as Patent Owner uses the term in the present proceedings.[3] We credit Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean what it says (i.e., to mean "lateral"), at least because it would have been reasonable for one of ordinary skill in the art to have construed a term (i.e., "lateral") with a common, accepted definition. Patent Owner's observation that a construction of the term "lateral" that was in use at the time of the invention included a "direct lateral" approach (as understood in this proceeding) further supports Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean "direct

[3] Dr. Jacobson testifies that "the phrase 'direct lateral' was not a phrase that I used in the technical parlance of my profession . . . at that time I had never heard the phrase 'direct lateral' to describe a 90 degree lateral approach to the spine. Instead, . . . I (and others) simply used the term 'lateral' when referring to a 90 degree lateral approach to the spine." Ex. 1030 ¶5.

lateral," as that term is presently construed in the instant proceedings. Also, we note that claim 17 does not recite the term "direct lateral," and Patent Owner does not assert that the '997 patent specification discloses the term "direct lateral." The absence of the term "direct lateral" in the '997 patent further supports that one of ordinary skill in the art at the time of the invention would not have used (or understood) the term "direct lateral."

In addition to Jacobson's explicit disclosure of, for example, "laterally inserting a cannula," Jacobson discloses figures that illustrate what Patent Owner now refers to as a "direct lateral" approach (i.e., lateral insertion along a path having an axis lying in a coronal plane). Ex. 1004, 2:26–27, Figs. 3–8. We note that in each of the figures of Jacobson, the outer side periphery of the instrument(s) inserted "laterally" into the intervertebral space, as illustrated, are depicted by parallel lines that are oriented at 90 degrees from a horizontal surface. Based on the depiction of the outer side contours of the instrument(s) as being oriented 90 degrees from a horizontal surface, one of ordinary skill in the art would have understood that the instrument(s) are perpendicular to an underlying horizontal surface in the superior-inferior perspective (with respect to the orientation of the patient). More importantly, as the outer side contours of the instruments are parallel in these perspectives, one of ordinary skill in the art would have understood the instruments, as illustrated by Jacobson, to be perpendicular to an underlying horizontal surface in the medial-lateral perspective (with respect to the orientation of the patient – i.e., that the orientation of the instrument(s) is "direct lateral," as Patent Owner uses that phrase, and not "posterolateral" or "anterolateral"). That is true because, assuming the instrument(s) illustrated in Jacobson are cylindrical, if the instrument(s) were angled away

from the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear farther away from each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which would be located farther away from the viewer). Likewise, if the instrument(s) were angled toward the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear closer to each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which is located closer to the viewer).

Moreover, as Petitioner's declarant (Dr. Paul McAfee) points out, an anterior cross sectional view of the instrument(s) in-situ (i.e., Ex. 1004, Fig. 6) shows an even and symmetrical view of the instruments throughout the length of the instrument(s). *See, e.g.*, Ex. 1029 ¶ 38. Dr. McAfee's testimony further supports that Jacobson discloses that the instruments are inserted along a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae, as recited in claim 17 (i.e., the "direct lateral" approach as presently understood in the instant proceedings).

Patent Owner argues that the figures as disclosed by Jacobson "appear to show a direct lateral path," but "do not clearly show the surgical approach" because the figures "are merely two-dimensional depictions [that depict the same orientation]" and that "these figures [of Jacobson] could just as likely disclose a posterolateral or anterolateral approach to the spine." PO Resp. 23–24 (citing Ex. 2038 ¶ 81). Patent Owner does not explain

adequately, however, how the anterior view of instrument(s) illustrated in Jacobson, with parallel outer side contours as described above or the anterior cross-sectional view of the instrument(s) throughout the length of the instrument(s) as also described above (i.e., instrument(s) that are normal to an underlying horizontal surface), "could just as likely" illustrate instrument(s) that are angled with respect to an underlying horizontal surface. While Patent Owner also argues that "surgeons are trained to orient an instrument in a patient's body by taking images of the instrument from multiple angles," Patent Owner does not demonstrate persuasively that, even if surgeons are trained to take images at multiple angles, that Jacobson illustrates that the instrument(s) are angled (i.e., a posterolateral or anterolateral approach). PO Resp. 24 (citing Ex. 2038 ¶ 81).

Patent Owner argues that Jacobson "discloses a method of performing percutaneous discectomy that implicates anatomical structures such as the spinal nerves and nerve root – structures that are encountered during a posterolateral (not direct lateral) approach to the spine" and a "stimulator [that] will cause motion in one of the patient's legs if it makes nerve contact [and that motor nerves are implicated only in a posterolateral approach.]" PO Resp. 19–20 (citing Ex. 2038 ¶¶ 76–77; Ex. 1004, 6:38–40). As Patent Owner indicates, Jacobson discloses "[t]o prevent nerve damage, a nerve stimulator . . . may be attached or passed down into the cannula or trocar to indicate if either instrument is hitting one of the spinal nerves or exiting nerve branches." Ex. 1004, 6:32–38. It is not disputed that Jacobson discloses a "lateral approach" that includes a "direct lateral" approach, as construed in the instant proceedings (see discussion above). Also, as described above, Jacobson discloses illustrations of a spinal fusion

procedure in which instruments are inserted into an intervertebral space (i.e., a "direct lateral" approach as presently understood) while oriented normal to an underlying horizontal surface (i.e., having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae). Patent Owner does not demonstrate sufficiently how Jacobson's further disclosure of the possible use of a "nerve stimulator" that indicates if an attached instrument contacts a nerve means that Jacobson does not disclose or suggest a lateral approach. For example, regardless of which approach Jacobson discloses, a "nerve stimulator" allegedly would be capable of detecting contact with a nerve because the functionality of a "nerve stimulator" would not be affected by whatever approach is disclosed by Jacobson.

Patent Owner argues that one of ordinary skill in the art would have understood that "the clearest path to a disc space is posterolaterally [and not direct lateral, as that term is used in these proceedings]." PO Resp. 21. Patent Owner further contends that Jacobson discloses "using a long spinal needle" to anesthetize the patient and that, based on this disclosure and the allegation that a posterolateral (and not "direct lateral") approach is the "clearest path" that avoids the bowel, one of ordinary skill in the art would have understood that Jacobson discloses a posterolateral approach and not a "direct lateral" approach. PO. Resp. 21–22. As previously described, however, Jacobson discloses a "lateral" approach, which includes a so-called "direct lateral" approach and illustrates such an approach. Patent Owner does not show persuasively that one of ordinary skill in the art, given these explicit teachings, would have understood that the apparent "direct lateral" approach of Jacobson is actually a "posterolateral" approach based on

Jacobson's disclosure of one choice of method of administering an anesthetic.

In any event, as Patent Owner indicates, Jacobson discloses a "go-no-go" indicator that determines if the needle can be used. If the needle of Jacobson cannot be used, "the procedure cannot be used on this particular patient." *Id*. at 21 (citing Ex. 1004, 5:23–36). In other words, Jacobson discloses that if the needle cannot be safely used on a particular patient, the procedure is not performed. Even assuming Patent Owner's contention to be correct that using a so-called "direct lateral" approach carries a risk of bowel perforation, Jacobson explicitly addresses any such potential complications of the procedure. Hence, we are not persuaded that the potential use (or non-use) of a needle in Jacobson would suggest to one of ordinary skill in the art of a particular route of entry of the needle in a patient.

Patent Owner argues that Jacobson discloses a procedure that "can 'be performed in approximately 15 minutes,'" and that one of ordinary skill in the art would have understood that performing the procedure using a "direct lateral" approach would have taken "significantly longer than" 15 minutes. *Id*. at 23 (citing Ex. 2038 ¶ 86). Based on this assumption, Patent Owner contends that Jacobson discloses a posterolateral approach. Jacobson discloses that "[i]nstruments constructed in accordance with the invention allow the procedure to be performed in approximately 15 minutes under only local anesthesia." Ex. 1004, 2:54–57.

Patent Owner's declarant (Dr. Barton L. Sachs) testifies that "[p]erforming such a procedure in 15 minutes is far more consistent with an approach that is [posterolateral] than one that is direct lateral" and that "[i]n my opinion, a direct lateral discectomy would take significantly longer than

15 minutes." Ex. 2038 ¶ 87. However, Dr. Sachs testifies that he is of the opinion that a 15 minute procedure is "consistent with" a posterolateral procedure, but does not assert or provide sufficient evidence to suggest that one of ordinary skill in the art would have understood that such a procedure taking 15 minutes or less would not have used the so-called "direct lateral" approach. In addition, even assuming Patent Owner's implication that performance of spinal fusion using the so-called "direct lateral" approach could never be completed within 15 minutes, we note that Dr. Sachs testifies that the so-called "direct lateral" approach takes longer than 15 minutes because such an approach "requires care to deal with anatomical structures such as the peritoneum, the bowel, vascular structures, and the psoas muscle." Ex. 2038 ¶ 87. Jacobson discloses that the procedure takes "approximately 15 minutes under only local anesthesia," suggesting that Jacobson's time estimate of 15 minutes would not include the time for administering anesthesia (or advancing a needle to administer the anesthetic). Hence, one of ordinary skill in the art would have understood that the alleged "rate-limiting" step (according to Dr. Sachs) of dealing with the bowel, for example, would not be included in Jacobson's time estimate of 15 minutes. Dr. Sachs (and Patent Owner) does not demonstrate that one of ordinary skill in the art would have understood that the so-called "direct lateral" approach must take longer than 15 minutes, even after the "anatomical structures" that Dr. Sachs cites are already "dealt with."

Patent Owner argues that Jacobson discloses "placement of a patient in a lateral decubitus position [that] does not necessarily mean his approach is directly lateral." PO Resp. 23. Patent Owner does not demonstrate sufficiently, however, that one of ordinary skill in the art would have

understood that placement of a patient in a lateral decubitus position would mean necessarily the approach is something other than the so-called "direct lateral" approach, particularly in view of the previously discussed disclosure of Jacobson suggesting to one of ordinary skill in the art that the approach disclosed is the so-called "direct lateral" approach.

Jacobson discloses that the surgical procedure is a "fusion" surgical procedure. Ex. 1004, 6:13. Petitioner states that "a 'fusion' procedure . . . necessarily includes the insertion of an implant into the disc space." Pet. 19. Hence, Petitioner argues that Jacobson discloses or suggests an implant. Patent Owner argues that a fusion surgical procedure "can be with or ***without*** an implant" and that an "[i]nherent disclosure by a prior art reference 'is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation.'" PO Resp. 25 (citing Ex. 2039, 26:23 – 27:1). Hence, Patent Owner argues that a fusion surgical procedure does not necessarily include the insertion of an implant.

Based on the record, we agree with Patent Owner that a "fusion" surgical procedure does not require the insertion of an implant in every instance. Therefore, we agree with Patent Owner that a "fusion" surgical procedure does not "necessarily" include the insertion of an implant. We disagree, however, with Patent Owner's implication of a requirement of showing a claim limitation is inherently present in a prior art reference to support a prima facie showing of obviousness of the disputed claims over a combination of references. For example, a "single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In the present case, the ground of

unpatentability in dispute is not "by anticipation." Hence, whether the "fusion" surgical procedure of Jacobson "necessarily" includes insertion of an implant has not been shown to be relevant to the present proceedings.

Brantigan – "implant being sized to occupy substantially the full transverse widths of the vertebral bodies"[4]

Claim 17 recites the length of an implant being sized to occupy substantially the full transverse widths of the vertebral bodies of the two adjacent vertebrae. Petitioner argues that Brantigan discloses or suggests this feature. *See, e.g.*, Pet. 28. Patent Owner argues that Brantigan discloses implants that are "***shaped*** to conform with the general outline perimeter of the vertebrae," but fails to disclose or suggest that "the implant is ***sized*** to trace the outline perimeter of the [vertebrae]." PO Resp. 34. As Petitioner points out, however, Brantigan discloses, for example, a "plug . . . generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column." Ex. 1006, 4:6–8. Hence, Brantigan discloses an implant that is both shaped and sized with regard to the disc space.

Patent Owner argues that Brantigan discloses an implant "that is designed to sit within the apophyseal ring" and "designed to sit in the central region of adjacent vertebral bodies where bone tends to be more cancellous and vascular." PO Resp. 36–37 (citing Ex. 1006, 2:15–16, Fig. 1; Ex. 2041, 1520:2–16; Ex. 2039, 50:1–10; Ex. 2038 ¶ 110). Hence, Patent Owner argues that Brantigan fails to disclose an implant that includes (or overlaps)

[4] Patent Owner argues that "[c]ollateral estoppel precludes Petitioner from relitigating its rejected interpretation of the disclosures of Brantigan." PO Resp. 39. After careful consideration, we are not persuaded by Patent Owner's arguments for at least the reasons previously stated. *See, e.g.*, Dec. on Inst. 13.

the apophyseal ring of a vertebral body or extends beyond a central region of a vertebral body. As previously described, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Patent Owner does not show that claim 17 also recites an implant being sized to extend onto the apophyseal ring of the vertebral body or an implant being sized to extend beyond a central region of a vertebral body. Nor does Patent Owner point to an explicit disclosure in the Specification regarding the length of the implant with respect to the alleged "apophyseal ring." We, therefore, are not persuaded by Patent Owner's contention.

Patent Owner argues that Brantigan discloses an implant "conforming in shape and size with opposing ***hard end plates*** of vertebrae'" that does not "include the outer periphery (or apophyseal ring) of a vertebral body" or "***the entire vertebral body***." PO Resp. 34 (citing Ex. 2038 ¶ 29). As an initial matter, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Hence, claim 17 requires that the implant occupy "a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount." Dec. on Inst. 9. Patent Owner does not demonstrate that claim 17 requires that the implant includes "the entire vertebral body."

Also, as discussed above, Brantigan discloses that the implant is "sized to conform with the disc space between adjoining vertebrae." Ex. 1006, 4:6–7. We construe the term "disc space" recited in claim 17 broadly but reasonably and in light of the Specification to include a space between adjacent vertebral bodies. We agree with Petitioner that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would have

occupied at least a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount (i.e., occupying "substantially" the full transverse width). Otherwise, an implant that does not occupy "substantially" the full transverse width would not have been sized to conform to the disc space, in contrast to Brantigan's disclosure that the implant is, in fact, sized to conform to the disc space.

Dr. Sachs testifies that the vertebral body contains a "vertebral endplate " that "is typically vascular," an "apophyseal ring" "anatomically distinct from the vertebral endplate" and "almost entirely avascular" located "[t]oward the vertebral periphery," and a "cortical rim" "distinct from the apophyseal ring" located "[a]t the very edge of the vertebral body." Ex. 2038 ¶ 29.

While Dr. Sachs provides testimony on the anatomy of the intervertebral space and disc, Dr. Sachs does not appear to provide testimony supporting Patent Owner's implied contention that one of ordinary skill in the art would have considered the term "occupying substantially the full transverse width of the vertebral body," as recited in claim 17, to mean "occupying no more than the width of the vertebral endplate" or "occupying (or not occupying) any portion of the apophyseal ring." Hence, even assuming that Dr. Sachs' characterization of the anatomy of the intervertebral disc space and vertebral bodies is correct, the testimony of Dr. Sachs provides insufficient evidence to refute the prima facie showing that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would occupy "substantially" the disc space (i.e., including a length that is less than the full transverse width of the vertebral bodies by an insubstantial

amount). In addition, even assuming claim 17 requires the length of the implant to overlap onto the "apophyseal ring" (claim 17 does not recite this requirement, however), the length of the implant of Brantigan would have included both the alleged "vertebral endplate" and the alleged "apophyseal ring" because both of these alleged structures overlie the space between adjacent vertebral bodies (i.e., the "disc space").

Patent Owner argues that Brantigan "expressly teaches an implant that is designed to sit within the apophyseal ring" as illustrated in Figure 10 of Brantigan, which, according to Patent Owner, "shows the implant 11 sitting well within the apophyseal ring." PO Resp. 36 (citing Ex. 1006 at Fig. 10). We note that Brantigan illustrates an implant within an intervertebral space in Figure 10; however, Patent Owner does not show persuasively that Brantigan "expressly teaches" that the implant illustrated in Figure 10 sits "within the apophyseal ring." For example, Brantigan does not appear to label any structure within Figure 10 as the "apophyseal ring." Nor does Patent Owner point to a disclosure in the textual portion of Brantigan indicating that the implant as illustrated in Figure 10 (or any other figure in Brantigan) sits "within the apophyseal ring." Indeed, as previously described, Brantigan appears to disclose the opposite (i.e., that the implant is "sized to conform with the disc space"). We, therefore, agree with Petitioner that one of ordinary skill in the art would not have understood that Brantigan discloses or suggests that the implant must not extend into the disc space encompassed by the apophyseal ring (not having been disclosed or suggested by Brantigan).

Patent Owner argues that "a figure in Brantigan . . . was admittedly drawn incorrectly." PO Resp. 36 (citing Ex. 2041, 1516:13–25, 1517:6–12;

Ex. 2039, 44:5–14). In particular, Patent Owner argues that Figure 11 of Brantigan allegedly contains discrepancies regarding the direction of insertion of the implant into the intervertebral space. *See, e.g.*, Ex. 2041, 1516:13–25. We are not persuaded by Patent Owner's argument at least because, even if Figure 11 discloses discrepancies regarding the direction of insertion of the implant, Patent Owner does not show persuasively that any such errors in Figure 11 sufficiently refute the prima facie case of obviousness that it would have been obvious to one of ordinary skill in the art to have provided an implant sized to occupy "substantially the full transverse widths of the vertebral bodies" given Brantigan's explicit disclosure that the implant is "sized to conform with the disc space."

Patent Owner argues that Brantigan discloses an implant that "can be rotated or reversed and still fit the vertebrae." PO Resp. 37 (citing Ex. 1006, 2:24–25; Ex. 2038 ¶ 113). Given that the implants of Brantigan are inserted "to support and fuse with adjacent vertebrae" (Ex. 1006, 1:65–66), we agree with Petitioner that one of ordinary skill in the art would have understood not to remove an implant once already inserted because doing so would not have permitted the implant to have provided the support desired or to have fused with adjacent vertebrae, as Brantigan discloses. Thus, we agree that one of ordinary skill in the art would have understood that Brantigan discloses that the implant of Brantigan may be selected to be inserted in any desired orientation (i.e., "rotated or reversed" prior to insertion so that the implant will "still fit the vertebrae").

In any event, regardless of which construction of "rotated or reversed and still fit the vertebrae" is used, as discussed previously, Brantigan discloses that the implant is "sized to conform with the disc space," which

one of ordinary skill in the art would have understood to mean sized to occupy substantially the full transverse widths of the vertebral bodies for reasons previously stated.

Patent Owner argues that Brantigan discloses "an anterior approach to the spine," as opposed to a lateral approach. PO Resp. 27. As previously discussed, Jacobson discloses or suggests this feature. We need not determine whether one of ordinary skill in the art would have understood Brantigan to also disclose this feature.

Leu – "interbody intraspinal implant"

Patent Owner argues that Leu discloses a "graft conglomerate" that, according to Patent Owner "is not a spinal fusion implant." PO Resp. 48 (citing Ex. 2038 ¶¶ 89, 97–99). Claim 17 recites an "interbody intraspinal implant." Patent Owner's declarant (Dr. Sachs) testifies that Leu discloses that the "graft conglomerate" contains "impacted bone" and "soft cancellous bone" that "is not a structural implant as claimed by the '997 [patent]." Ex. 2038 ¶ 97. Hence, Patent Owner appears to argue that one of ordinary skill in the art would have understood that an "interbody intraspinal implant," as recited in claim 17, must not contain "impacted bone" or "soft cancellous bone" such that the implant is not a "structural implant."

Patent Owner does not demonstrate that claim 17 recites that the "interbody intraspinal implant" must not contain "impacted bone" or "soft cancellous bone." Nor does Patent Owner indicate that the '997 patent specification discloses this explicit definition of the term. While Patent Owner's declarant (Dr. Sachs) testifies that "this graft conglomerate [of Leu] is not a structural implant as claimed by the '997 [patent]," Ex. 2038 ¶ 97,

Petitioner's declarant (Dr. McAfee) testifies that "nothing in Leu's suggestion for the 'porous apatite' graft . . . required an ordinary spinal surgeon . . . to limit his or her thoughts only to 'bits of porous apatites'" and that "spinal surgeons of ordinary skill understood that various non-bone elements were inserted into the disc space as part of conventional interbody fusion." Ex. 1029 ¶ 57. Hence, even if one of ordinary skill in the art would have understood that an "interbody interspinal implant," as recited in claim 17, must have provided structural support and that a "graft conglomerate" containing only "impacted bone" and "soft cancellous bone" would have provided insufficient structural support to be characterized as an "interbody intraspinal implant" (as Dr. Sachs testifies), we credit Dr. McAfee's testimony that one of ordinary skill in the art would have also understood that "non-bone elements were inserted into the disc space as part of conventional interbody fusion," to provide sufficient structural support to be classified as an "interbody interspinal implant."

In any event, Dr. McAfee also testifies that it would have been obvious to one of ordinary skill in the art to have "employ[ed] an implant structure *having a size/structure suggested by Brantigan* in the resulting surgical method of Jacobson in view of Leu." Ex. 1029 ¶ 57. Hence, Petitioner and Dr. McAfee argue that Brantigan also discloses an "interbody intraspinal implant," as recited in claim 17. Patent Owner does not appear to contest Petitioner's contention.

"Elongated portion"

Patent Owner argues that Jacobson fails to disclose or suggest an "elongated portion," as recited in claim 17 because, according to Patent

Owner, "[t]hese portions [as disclosed by Jacobson] are not 'positioned over' adjacent vertebrae." PO Resp. 50. Petitioner explains that Jacobson discloses "wires [that] are indeed positioned over the vertebrae." Pet. Reply 12, *see also* Pet. 26–27; Ex. 1029 ¶¶ 54–55. As Petitioner explains, Jacobson appears to disclose anchor wires (i.e., "elongated portions") that are positioned over adjacent vertebrae. Ex. 1030, Fig. 5. Patent Owner does not provide sufficient evidence of specific differences between the "elongated portion" being "positioned over" adjacent vertebrae, as recited in claim 17, and the "anchor wires" (that are "elongated portions") that are also "positioned over" adjacent vertebrae. We, therefore, are not persuaded by Patent Owner's argument.

Jacobson, Leu, Brantigan - combinability

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Jacobson, Leu, and Brantigan. PO Resp. 50–53. Jacobson discloses advancing instruments laterally into the disc space to perform a "fusion" procedure. Ex. 1004, 5:1–4, 6:11–13. Leu discloses fusion of the lumbar spine by introducing an "interbody graft" into the disc space. Ex. 1005, p. 603. Brantigan, like Leu, discloses "prosthetic implant devices" that are "suitable for . . . lateral placement in any area of the spine." Ex. 1006, 2:56–58. We agree with Petitioner that the combination of the known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than the predictable and expected result of performing a spinal fusion procedure

(Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

Patent Owner argues that one of ordinary skill in the art would not have combined the teachings of Jacobson with Leu because "the sequential dilators [of Leu] would *widen the perforation* [caused by a needle puncture to the patient's intestines] without any warning to the surgeon." PO Resp. 51. We are not persuaded by Patent Owner's argument at least because none of Jacobson or Leu supports the contention made.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because, according to Patent Owner, Brantigan "teaches away from sizing an implant to rest on the apophyseal ring or be sized to occupy substantially the full transverse width of adjacent vertebral bodies." PO Resp. 51–52, 55–56. This issue was discussed previously above.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because the "cannulae disclosed by Jacobson and Leu are too narrow to accommodate Brantigan's implant," that "a person of ordinary skill in the art would not be able to insert [Brantigan's] implant in Jacobson's [system]," and that "the shape of the Brantigan implant is not conducive to insertion through a cannula or similar surgical instrument [as disclosed by Jacobson or Leu]." PO Resp. 52–53. In other words, Patent Owner argues that the combination of Jacobson, Brantigan, and Leu would

not have been obvious to one of ordinary skill in the art because the prior art systems are not physically combinable (i.e., Brantigan's implant allegedly cannot be physically combined with the cannula of either Jacobson or Leu). "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."). We are thus not persuaded by Patent Owner's argument.

Secondary considerations

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Commercial Success

Patent Owner argues non-obviousness based on alleged commercial success of the claimed invention. PO Resp. 56–57. Patent Owner contends that Petitioner's product (i.e., the "XLIF procedure and CoRoent XL implants") and Patent Owner's product (i.e., the "DLIF procedure and

Clydesdale and Capstone L implants") have "enjoyed tremendous commercial success," based on "100,000 spinal levels" having been treated since 2003, sales of Petitioner's product of "$250M from May 2004 to June 2010," and sales of Patent Owner's product of over "$50M over approximately the same time period." PO Resp. 56–57 (citing Ex. 2038 ¶ 136; Ex. 2045, 47; Ex. 2046–2048).

Even assuming the sales figures quoted by Patent Owner for both Petitioner's product and Patent Owner's product are correct, and assuming that these sales figures represent "commercial success," Patent Owner has not demonstrated a sufficient nexus between the merits of the claimed invention and the evidence offered. Patent Owner contends that "in order to encourage surgeons to select its product, Petitioner touts the CoRoent XL implant as having the patent features of the '997 patent, such as a 'large foot print,' 'spans ring apophysis,' and 'maximizes fusion surface area.'" PO Resp. 57 (citing Ex. 2049, 21). We note that Patent Owner does not show that any of "large foot print," "spans ring apophysis," or "maximizes fusion surface area" is recited in the claims of the '997 patent. Not having identified any specific features in the claims of the '997 patent that form the basis for the commercial success of Petitioner's product, Patent Owner does not show persuasively a nexus between the claimed invention and the evidence proffered.

In addition, even assuming that these features are recited in the claims of the '997 patent, Patent Owner still does not demonstrate a sufficient nexus between these specific alleged features and the evidence relied upon to demonstrate commercial success (i.e., sales figures). Upon review of the marketing materials cited by Patent Owner, we observe that in addition to a

"large foot print," "spans ring apophysis," and "maximizes fusion surface area," the marketing materials also allege other benefits of the marketed product such as "minimal soft tissue/muscle damage," "reduced post-operative morbidity," "outpatient or 23 hr procedure," "adequate exposure," "safe and reproducible," and "meet or exceed traditional results." Ex. 2049, 17. Patent Owner provides insufficient evidence to show which of these alleged benefits of the marketed product (if any) would have resulted in (i.e., had a "nexus" to) the "commercial success" (i.e., sales revenue) alleged by Patent Owner.

Industry Praise

Patent Owner argues non-obviousness based on "industry praise" allegedly attributed to the claimed invention. PO Resp. 58–59. Industry praise must also be linked to the patented invention. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010). Patent Owner cites to "Back.com," in which Dr. Richard Hynes states the benefits of the DLIF [Direct Lateral Interbody Fusion] procedure are that "you're approaching the disc from the side rather than from the front or back." Ex. 2050, p. 3. Petitioner has demonstrated that this feature (i.e., "direct lateral" approach), as discussed above, is disclosed by Jacobson. Hence, the feature that is allegedly praised was already present in the prior art. Under those circumstances, any evidence of secondary considerations stems from what was known in the prior art, so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If [secondary considerations are] due to an element in the prior art, no nexus exists.").

Dr. Hynes alleges additional benefits of DLIF including "a very small, 1-2 cm incision," no "big incisions," no "cutting through muscles," "patients were in and out of the OR in less than an hour," and there was "major stabilization with no blood loss." Ex. 2050, p. 3. Patent Owner does not demonstrate sufficiently that any of these additional allegedly praiseworthy features are recited in the '997 patent claims. Hence, Patent Owner fails to demonstrate sufficiently a nexus between the alleged praise and the claimed invention.

Patent Owner also cites to Rose Mary Budge, "A New Solution," 2004–2009, available at http://www.spinaldoc.com/NuVasive_Spinal_Surgery.php. ("Budge," Ex. 2051). Budge discloses the procedure "involves side entry to the surgical [site] rather than from the back or the front." Ex. 2051 at 1. As previously described, this "praise," to the extent that this objective statement of the direction of entry to the surgical site can be considered "praise" at all, was known in the prior art (e.g., Jacobson), so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

Budge further states other benefits of the procedure, including that the procedure is "less intimidating than the traditional methods," "can significantly lessen collateral damage," causes "less tissue trauma, less scarring, less blood loss and less post-operative discomfort." Ex. 2051 at 1. As previously described, Patent Owner does not show sufficiently a nexus between any of these additional allegedly praiseworthy features and the claimed invention because Patent Owner does not demonstrate that any of these features are recited in the claims of the '997 patent.

Patent Owner also cites to PR Newswire, "26 Technologies Receive 2009 Spine Technology Awards," 2009 ("PR Newswire," Ex. 2052) as demonstrating that "Petitioner's XLIF was selected as a 'Best New Technology for 2009' by Orthopedics This Week, an industry publication, and won an award in the "Minimally Invasive Care' category." PO Resp. 58. Even assuming that the "XLIF" won an award as Patent Owner asserts, Patent Owner does not show sufficiently that this award (or praise) had a nexus to a claim feature of the '997 patent (or which claim feature that might be).

Patent Owner further argues that Dr. Michelson testifies that Mr. Larry Boyd (presumably an officer at Sofamor Danek) had, for the first time, "seen a lateral retroperitoneal [approach]" at some point in time. PO Resp. 59 (citing Ex. 2041, 195:24 – 196:2). According to Patent Owner, officers at Sofamor Danek were "'very excited' about Dr. Michelson's technology and moved quickly to acquire it by signing a license agreement." PO Resp. 59 (citing Ex. 2041, 68:7–15). Patent Owner does not provide sufficient evidence explaining what features caused officers at Sofamor Danek to become "very excited" or why the officers allegedly "moved quickly" to sign a license agreement or how any alleged excitement or speed in the signing of license agreements pertains to specific features recited in claim 17. Hence, Patent Owner does not show a sufficient nexus between the claimed invention and the activities alleged to constitute "praise."

Copying

Patent Owner argues non-obviousness based on alleged copying of the claimed invention by competitors. PO Resp. 59–60. "[C]opying by a

competitor may be a relevant consideration in the secondary factor analysis." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (citing *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed.Cir.1984). "[A] nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (internal quotation omitted). Copying as objective evidence of nonobviousness requires evidence of effort to replicate a specific product. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Iron Grip*, 392 F.3d at 1325. Generally, evidence of alleged copying may be given little weight when the copy is not identical to the product embodying the claimed invention. *See Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985).

Patent Owner asserts that Petitioner "worked on an early lateral access project called 'ELIF,' which stood for Extreme Lateral Interbody Fusion," trademarked the term "XLIF—for eXtreme Lateral Interbody Fusion" for the product, and eventually "evolved into a profitable company." PO Resp. 60 (citing Ex. 2041, 329:14–25, 434:2 – 435:14, 573:9 – 574:5, 979:19–24). Patent Owner also states that "prototypes created by Dr. Michelson included an implant with a 42 mm length, a distractor, outer sleeve, and other instruments." PO Resp. 60 (citing Ex. 2004). Patent Owner does not demonstrate sufficiently that the alleged copy (i.e., "ELIF" or "XLIF") is identical to the product embodying the claimed invention. Therefore, little weight is accorded to Patent Owner's allegations of copying. To the extent that Patent Owner argues that the "ELIF" or "XLIF" systems utilize implants

measuring 42 mm in length, a distractor, outer sleeve, and "other instruments," Patent Owner does not demonstrate that such a system embodies the claimed invention. For example, Patent Owner does not show that any of the claims of the '997 patent recite that the implant measures 42 mm in length and does not explain what the "other instruments" entail.

We have considered the evidence presented, but do not discern that it adequately establishes that the pertinent products are replications of a product that includes all the features of claim 17 of the '997 patent. In any event, even assuming that the noted "ELIF" or "XLIF" products do incorporate all the features of claim 17, it is not the case that "every competing product that arguably falls within the scope of a patent is evidence of copying." *IronGrip*, 392 F.3d at 1325. Rather, as noted above, copying requires the "replication" of a specific product. *Id*.

Patent Owner does not provide additional arguments or evidence with respect to claims 18–22. We are persuaded, by a preponderance of the evidence, that claims 17–23 are unpatentable over the combination of Jacobson, Leu, and Brantigan.

B. Grounds Based at least in part on Jacobson, Leu, and Michelson '247 (Claims 9–16 and 24–30)

Claim 9 recites the length of an implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Claim 24 recites the length of an implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae. Michelson '247 discloses "an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc" in which a drill is used that is "such a length that it can not

penetrate more than **28** millimeters beyond the end of the drill sleeve" so that "the implant . . . is able to be inserted only 28 millimeters." Ex. 1008, 1:5–7; 9:40–42; 10:31–32. Michelson '247 also discloses that "the implant . . . is only 26 millimeters in length . . . [which] guarantees that the implant . . . will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal." Ex. 1008, 10:32–36. While Michelson '247 discloses an implant that measures 26 millimeters in length and is inserted into a drilled opening that is 28 millimeters in length, Petitioner does not demonstrate sufficiently that Michelson '247 also discloses that the implant must occupy either substantially the full transverse width of the vertebral body (as recited in claim 9) or the full transverse width of the vertebral body (as recited in claim 24). For example, Michelson '247 merely discloses a specific length of 26 millimeters for the length of the implant (26 millimeters) and a specific length of a drilled opening (28 millimeters), but does not disclose the length of the implant (or opening) in relation to the size of the vertebral body.

Michelson '247 further discloses that the drill may be "varied and made smaller for enhanced safety," but does not appear to disclose elongating the drill to a length greater than 28 millimeters. Ex. 1008, 9:42–43. That further demonstrates that Michelson '247 fails to disclose or suggest sizing the implant to obtain the maximum sized implant with respect to the size of the vertebral body. Instead, Michelson '247 appears to suggest using only smaller sized implants "for enhanced safety."

Petitioner argues that Michelson '247 discloses "the length of the implant extend[s] longitudinally across nearly the full disc space along the direction of insertion." Pet. 10. Regarding claim 24, Petitioner does not

assert or demonstrate sufficiently that Michelson '247 discloses or suggests an implant sized to occupy the *full* transverse width of the vertebral bodies. In any event, as Patent Owner points out, "there is ***nothing in the written disclosure*** of Michelson '247 that teaches a surgeon to size an implant to span as much of the length as possible from an anterior to posterior direction." PO Resp. 41 (citing Ex. 2039, 44:16–19; 45:6–16). Petitioner does not point out where specifically Michelson '247 discloses or suggests this feature.

Petitioner argues that Patent Owner does not argue Michelson '247 discloses an implant that would not rest on the apophyseal ring or that the implant is designed to rest only on a spongy center part of the vertebrae and that "the '997 patent's drill has the very same feature [as the drill disclosed by Michelson '247]." Pet. Reply 11. Even assuming Petitioner's allegations to be correct, Petitioner still does not demonstrate persuasively that Michelson '247 discloses or suggests an "implant being sized to occupy the full" (or "substantially full") dimension of the vertebral body, as recited in claim 9 or claim 24.

Claims 10–16 depend from claim 9 and claims 25–30 depend from claim 24. We are not persuaded that claims 9–16 and 24–30 would have been obvious over the combination of Jacobson, Leu, and Michelson '247.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the following documents:

1. Declaration of Dr. Paul McAfee ("McAfee Declaration," Ex. 1001, 54–85);
2. Affidavit of Henry Vernon Crock (Ex. 1014–1021);

3. Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶¶ 4, 7, 9, 10, 37–39, 43–45, 48, and 49);
4. Declaration of Dr. Robert E. Jacobson ("Jacobson Declaration," Ex. 1030 ¶¶ 4–6, 8, and 10);
5. Declaration of Patrick Miles ("Miles Declaration," Ex. 1032 ¶ 9);
6. William A Friedman, *Percutaneous Discectomy: An Alternative to Chemonucleolysis?*, NEUROSURGERY, Vol. 13, No. 5 (1983) ("Friedman Article," Ex. 1036);
7. Steven L. Kanter and William A. Friedman *Percutaneous Discectomy: An Anatomical Study*, NEUROSURGERY, Vol. 16, No. 2 (1985) ("Kanter Article," Ex. 1037);
8. Medtronic Corporate Structure (Ex. 1046);
9. Gregory M. Malham, et al., *Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions*, THE SCIENTIFIC WORLD JOURNAL (2012) ("Malham Article," Ex. 1049);
10. Armen R. Deukmedjian, *Bowel and Vascular Injury Following 13,000 Lateral Interbody Fusions*, SMISS 2013 ANNUAL CONFERENCE ("Deukmedjian Article," Ex. 1050); and
11. Paul C. McAfee, et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, SPINE, Vol. 23, No. 13 (1998) ("McAfee Article," Ex. 1067).

For the reasons discussed below, the motion is dismissed.

Second Declaration of Dr. Paul McAfee – Ex. 1029 ¶ 38

Patent Owner alleges that the Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶ 38) should be excluded because, according to Patent Owner,

"Dr. McAfee wrongly relies on Dr. Jacobson's declaration (Exhibit 1030) about the alleged surgeries he performed prior to 1995," that "Dr. McAfee wrongly relies on the Crock Affidavit (Exhibit 1014) in paragraphs 7 and 9 of his second declaration about the surgeries Dr. Crock allegedly performed prior to 1995," which, according to Patent Owner, "are not relevant to whether the challenged claims are unpatentable in light of the prior art patents and printed publications in the instituted claims." Paper 53 at 6.

The Second Declaration of Dr. Paul McAfee, however, is not relied upon for any alleged surgeries performed by Dr. Crock or Dr. Jacobson prior to 1995 (or at any other time). Rather, the Second Declaration of Dr. Paul McAfee is relied upon to support what one of ordinary skill in the art would have understood based on Figure 6 of the '997 patent at the time of the invention (see above). Ex. 1029 ¶ 38. Thus, we are not persuaded that the Second Declaration of Dr. Paul McAfee (at ¶ 38) should be excluded.

Jacobson Declaration – Ex. 1030 ¶ 5

Patent Owner moves to exclude the Jacobson Declaration (Ex. 1030 ¶ 5) based on various bases. Patent Owner alleges that the Jacobson Declaration (Ex. 1030 ¶ 5) "include[s] what Dr. Jacobson was allegedly ***doing*** prior [to] 1995, not what the Jacobson '374 reference discloses to a person of ordinary skill in the art." Paper 53, 9–10.

The Jacobson Declaration (Ex. 1030 ¶ 5) is relied upon to ascertain what one of ordinary skill in the art would have understood by the terms "lateral" and "direct lateral" at the time of the invention (see above) and is not relied upon for any procedures Dr. Jacobson may or may not have been

alleged to have performed prior to 1995. Thus, we are not persuaded that the Jacobson Declaration (at ¶ 5) should be excluded.

Other Evidence

As previously described, Patent Owner moves to exclude other evidence, none of which was relied upon by the Board. Therefore, Patent Owner's motion to exclude is moot with respect to the other evidence.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 17–23 are unpatentable over Jacobson, Leu, and Brantigan under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claims 9–16 are unpatentable over Jacobson, Leu, McAfee, and Michelson '247 under 35 U.S.C. § 103(a) or that claims 24–30 are unpatentable over Jacobson, Leu, and Michelson '247 under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 17–23 of the '997 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00206
Patent 8,251,997 B2

PETITIONER:

Stephen Schaefer
Michael Hawkins
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Paper 67
Date: August 28, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00206
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

DECISION
Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. BACKGROUND

NuVasive, Inc. ("Petitioner") requests reconsideration of the Board's final written decision ("Decision" or "Dec."), dated July 10, 2014 (Paper 65). In the Decision, we determined that Petitioner has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of US Patent No. 8,251,997 B2 ("the '997 patent"), which is assigned to Warsaw Orthopedic, Inc. ("Patent Owner"), are unpatentable. Dec. at 36.

We have considered Petitioner's request, but we decline to modify the final written decision.

II. STANDARD OF REVIEW

A party challenging a final written decision by way of a request for rehearing must identify specifically all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d). The challenging party bears the burden of showing that the decision should be modified. *Id*.

III. DISCUSSION

Claim 9 recites "the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." Petitioner argues that we "overlook[ed] or misapprehend[ed] the clear teachings of Michelson '247 (particularly Figure 5 and col. 5, lines 1-7)" in concluding that Michelson '247 fails to disclose or suggest this feature. Req. Reh'g. 3. We disagree with Petitioner.

Michelson '247 discloses that "the present invention offers . . . greater surface area [as compared to the BAGBY device] to distribute the load" and is

"placed bilaterally where the bone tends to be more cortical and much stronger." Ex. 1008, 5:2-7. Contrary to Petitioner's contention, Michelson '247 merely discloses a device with greater surface area than the "BAGBY device" and that the device is placed bilaterally. Petitioner does not show sufficiently that Michelson '247 also discloses that the implant is sized to occupy substantially the full transverse width of the vertebral bodies. Regarding Figure 5, we note that Michelson '247 merely discloses that Figure 5 is "a sectional view of the vertebra structure, taken along lines 5—5 of FIG. 4." Ex. 1008, 7:61-62. Petitioner does not show sufficiently that Michelson '247 discloses that Figure 5 is drawn to scale or any specific measurements of the components illustrated therein. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)).

As previously discussed in the Decision, Michelson '247 discloses "an implant that measures 26 millimeters in length [that] is inserted into a drilled opening that is 28 millimeters in length." Decision 32. Petitioner does not show persuasively that Michelson '247 discloses that the device is sized at 26 millimeters or that the drilled opening is sized at 28 millimeters in order to be sized to occupy substantially the full transverse width of the vertebral bodies. In fact, Michelson '247 does not disclose the size of the vertebral bodies at all. Hence, Michelson '247 does not disclose or suggest that the implant is sized to occupy substantially the full transverse width of the vertebral bodies. At best, Michelson '247 merely discloses that the implant is sized to measure 26 millimeters without regard to the size of the vertebral bodies, as previously explained in the Decision.

Petitioner argues that Michelson '247 discloses that "**the present device is placed bilaterally <u>where the bone tends to be more cortical and much stronger out towards the rim</u>**." Req. Reh'g. 4. Petitioner contends that this disclosure indicates that Michelson '247 discloses an implant that is sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, as recited in claim 9. We disagree. Rather, Michelson '247 discloses that a device is placed bilaterally, which refers to the location at which the device is placed (i.e., bilaterally) and does not refer to the size of device (i.e., whether the device is sized to occupy substantially the full transverse width of the vertebral bodies or not).

Petitioner further argues that the Decision overlooks or misapprehends that the combination of Michelson '247 and Jacobson discloses or suggests an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, as recited in claim 9. Req. Reh'g. 6-8. In particular, Petitioner argues that "Jacobson supplies the teaching of the lateral approach." Req. Reh'g. 7. As described in the Decision and reiterated above, Michelson '247 fails to disclose or suggest an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Petitioner does not contend that Jacobson discloses or suggests an implant sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Hence, Petitioner has not shown sufficiently how either Michelson '247 or Jacobson discloses or suggests this claim feature. Petitioner does not explain sufficiently how this feature would have been obvious to one of ordinary skill in the art in view of the lack of such a suggestion in any of the cited references.

Petitioner further argues that claim 9 would have been obvious to one of ordinary skill in the art given that Michelson suggests the use of "**a longer**

threaded fusion implant" and that "a fusion implant . . . should extend long enough to rest on the cortical bone towards the outer rim." Req. Reh'g. 8, 11. However, Petitioner does not demonstrate sufficiently that Michelson '247 discloses or suggests these features. Rather, Michelson '247 appears to disclose merely an implant measuring 26 millimeters in length that is inserted into a drilled opening that is 28 millimeters in length. In any event, claim 9 recites the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Claim 9 does not recite "a longer threaded fusion implant" or an implant that "extends long enough to rest on the cortical bone towards the outer rim." Thus, even assuming that Michelson '247 discloses or suggests a longer threaded fusion implant that extends long enough to rest on the cortical bone towards the outer rim, we are still not persuaded by Petitioner's argument.

Claim 24 recites the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae. In the Decision, we concluded that Petitioner did not "assert or demonstrate sufficiently that Michelson '247 discloses or suggests an implant sized to occupy the *full* transverse width of the vertebral bodies." Decision 32–33. Petitioner argues that "under a broadest reasonable construction standard [the term "full transverse width," as recited in claim 24, should be construed] to be the same as the phrase 'substantially the full transverse width' in claim 9." Req. Reh'g. 13. We need not further consider Petitioner's proposal to construe the term "full" (as recited in claim 24) to mean "substantially full" because Petitioner does not show persuasively that the asserted combination of references discloses or suggests an implant being sized to occupy either the full width (claim 24) or substantially the full transverse width of the vertebral bodies, as recited in claim 9.

Petitioner does not provide additional arguments in support of claims 10-16 or 25-30.

IV. CONCLUSION

For at least the reasons given, we determine that Petitioner has not carried its burden of demonstrating that the Board misapprehended or overlooked any matters in rendering the final written decision. We decline to modify the final written decision.

V. ORDER

Accordingly, it is

ORDERED that the request for rehearing is denied.

IPR2013-00206
Patent 8,251,997 B2

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(12) **United States Patent**
Michelson

(10) **Patent No.: US 8,251,997 B2**
(45) **Date of Patent: Aug. 28, 2012**

(54) **METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE**

(75) Inventor: **Gary Karlin Michelson**, Venice, CA (US)

(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/306,583**

(22) Filed: **Nov. 29, 2011**

(65) **Prior Publication Data**

US 2012/0071984 A1 Mar. 22, 2012

Related U.S. Application Data

(60) Continuation of application No. 10/371,757, filed on Feb. 21, 2003, now Pat. No. 8,066,705, which is a continuation of application No. 08/480,461, filed on Jun. 7, 1995, now Pat. No. 7,491,205, which is a division of application No. 08/394,836, filed on Feb. 27, 1995, now Pat. No. 5,772,661.

(51) **Int. Cl.**
A61F 17/56 (2006.01)

(52) **U.S. Cl.** **606/53**; 606/60; 606/246

(58) **Field of Classification Search** ..... 606/53, 606/60, 86 A, 246–250, 61; 623/16, 17
See application file for complete search history.

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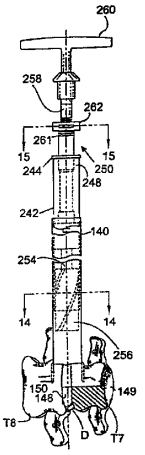
(57) **ABSTRACT**

A method for inserting an artificial implant between two adjacent vertebrae along a coronal plane.

30 Claims, 14 Drawing Sheets



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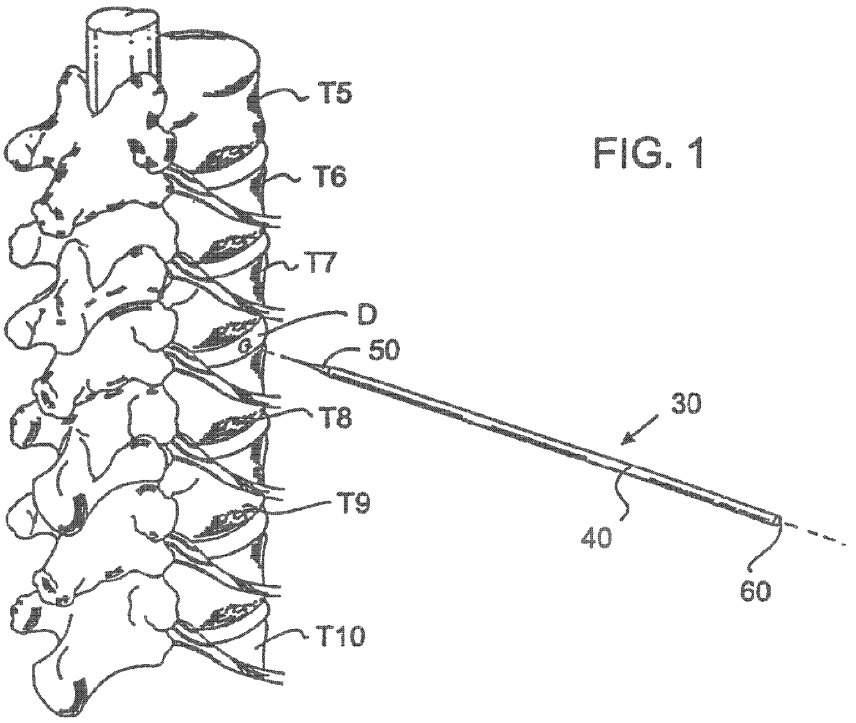
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T10

FIG. 1

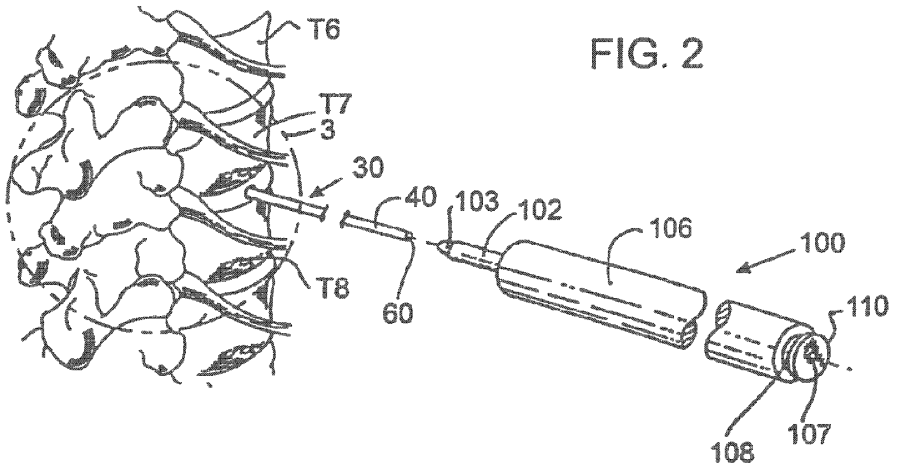
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FIG. 2

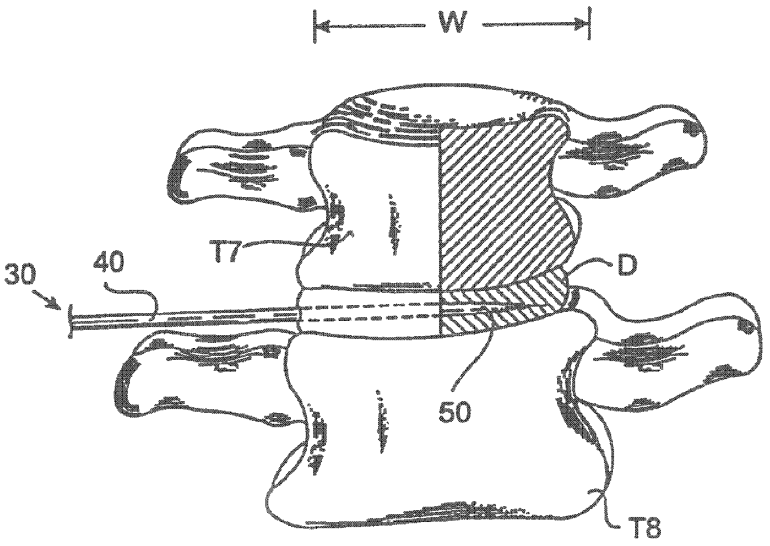

FIG. 3

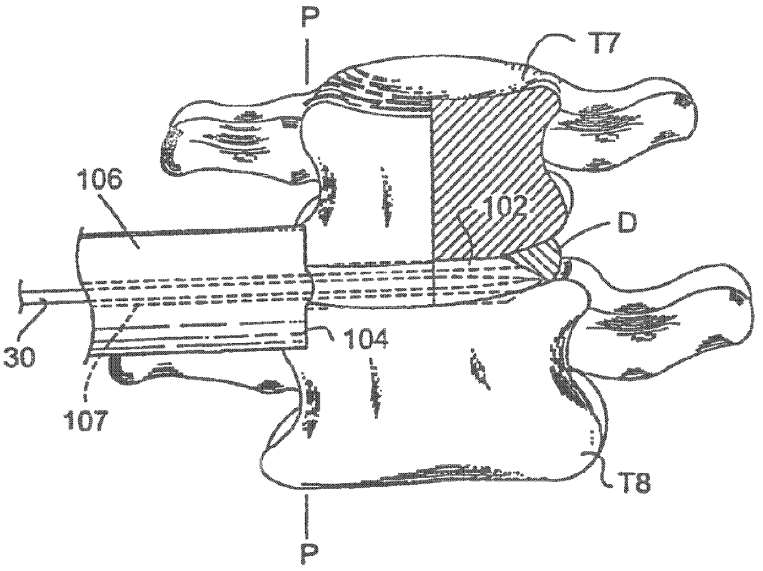

FIG. 4

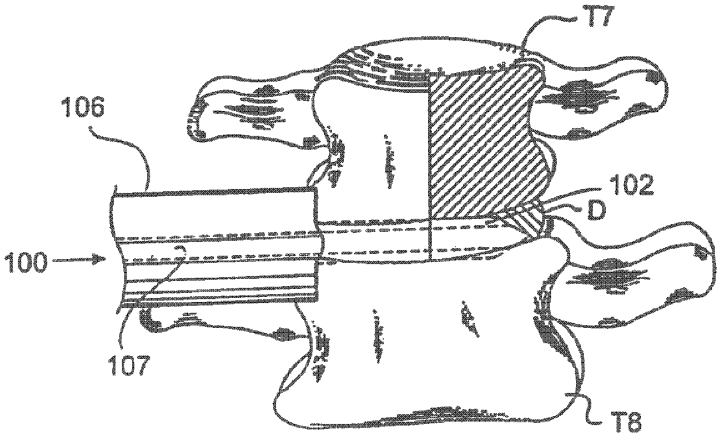

FIG. 5

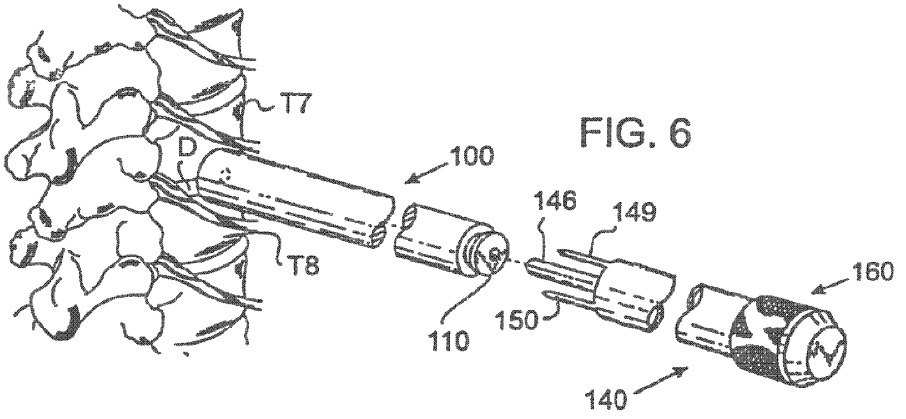

FIG. 6

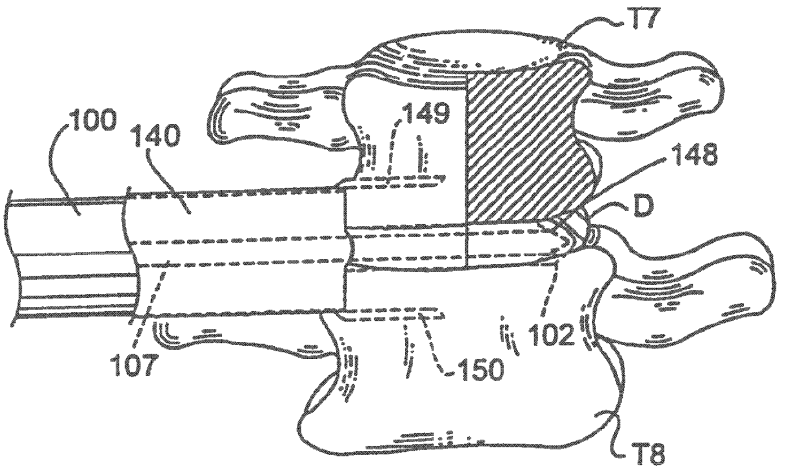

FIG. 7

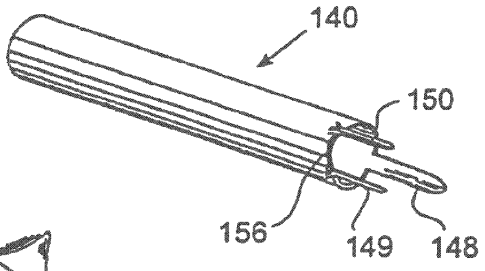

FIG. 7A

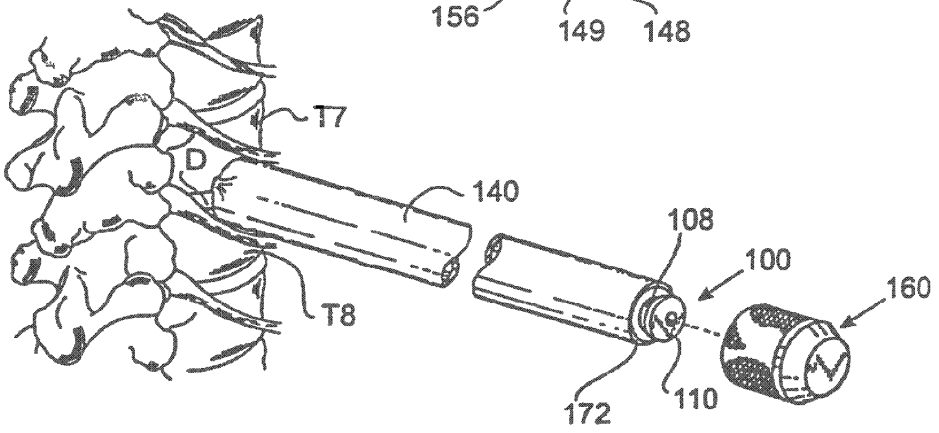

FIG. 8

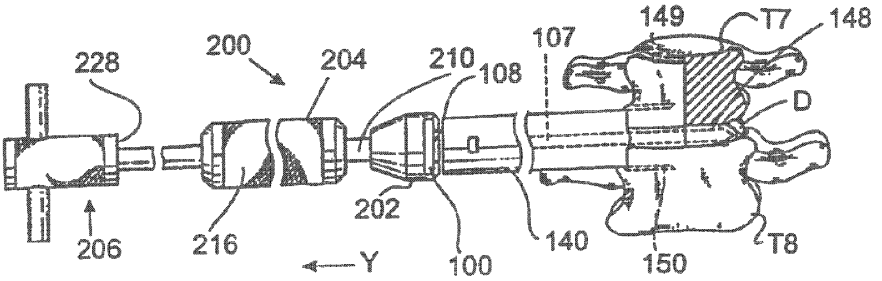
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FIG. 9

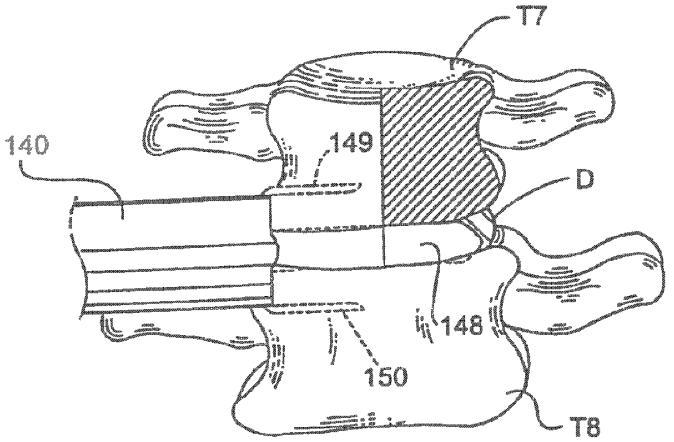
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FIG. 10

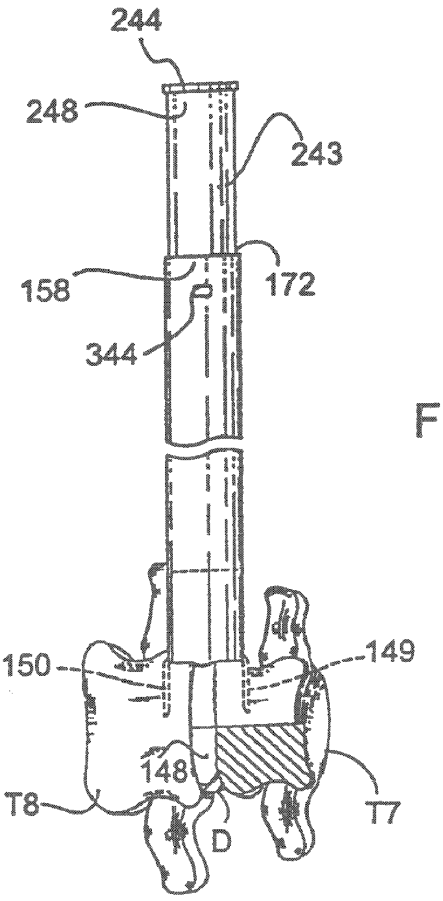
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FIG. 11

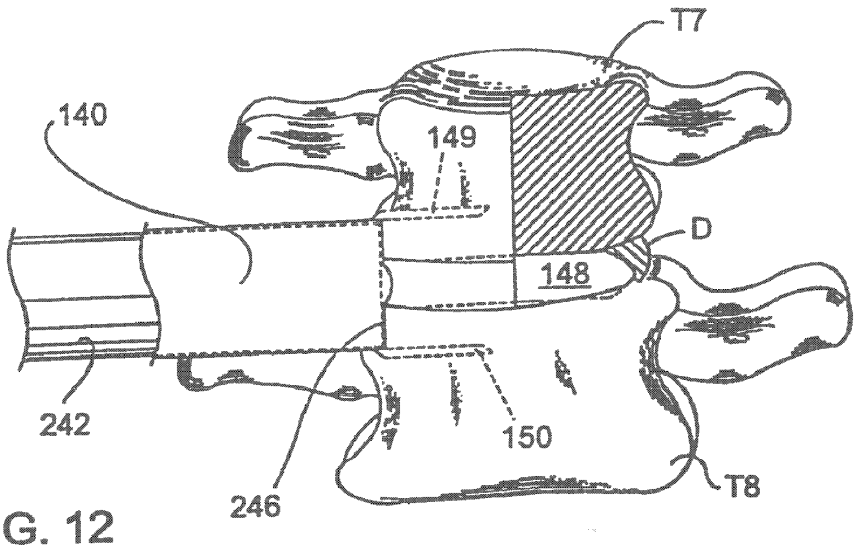
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FIG. 12

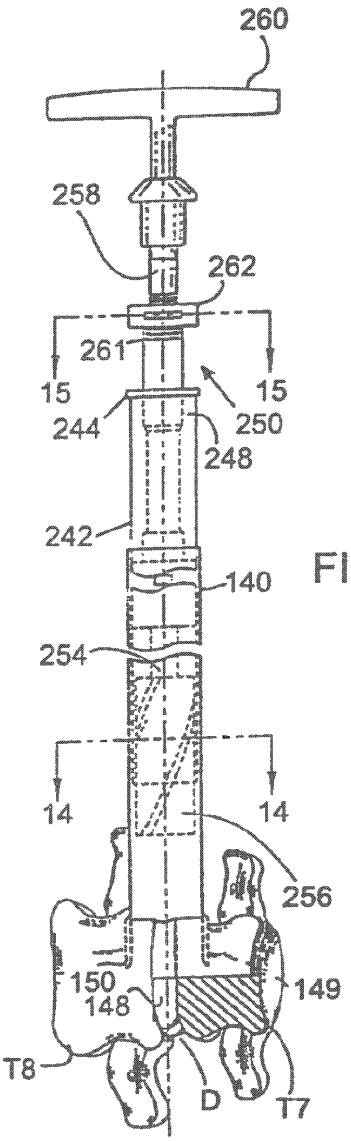

FIG. 13

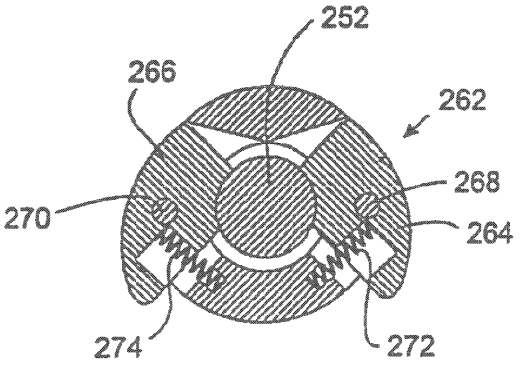

FIG. 15

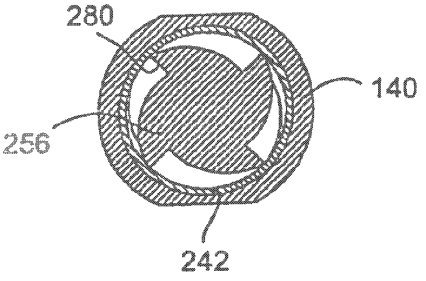

FIG. 14

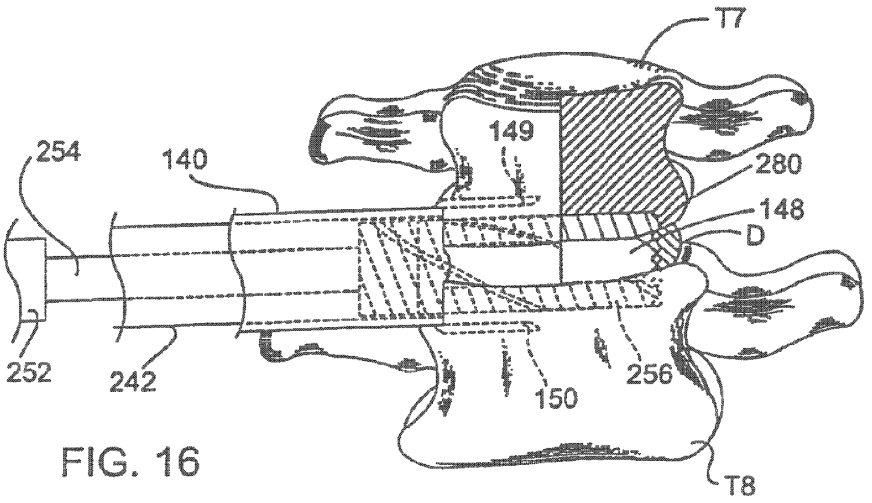
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FIG. 16

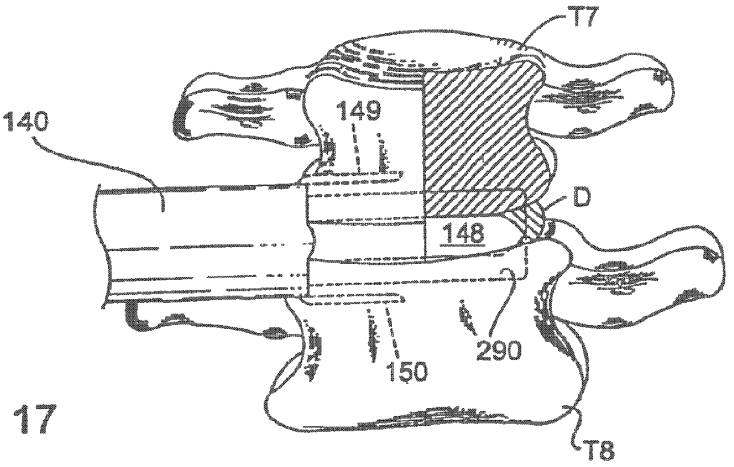
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FIG. 17

FIG. 18

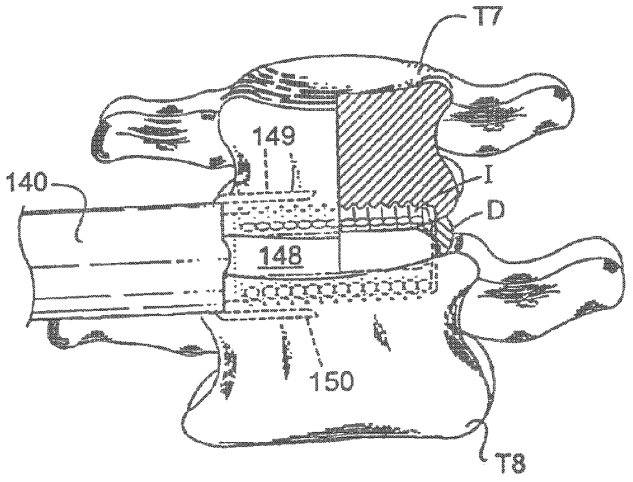
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FIG. 19

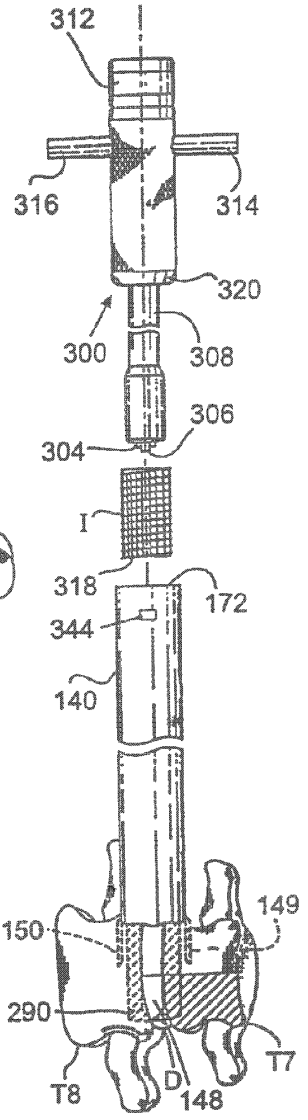
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FIG. 21

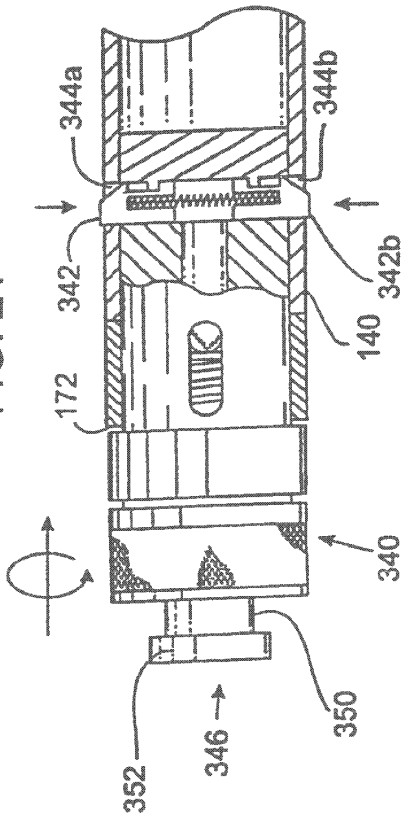
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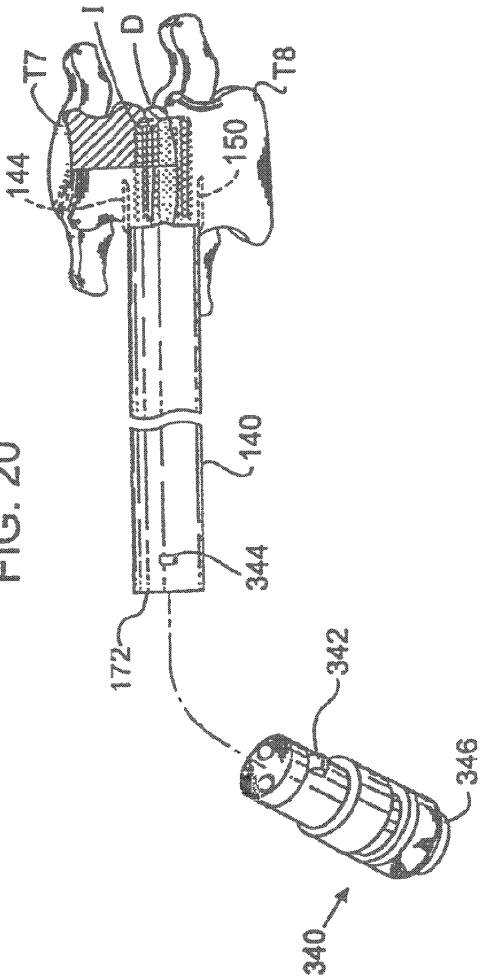
FIG. 20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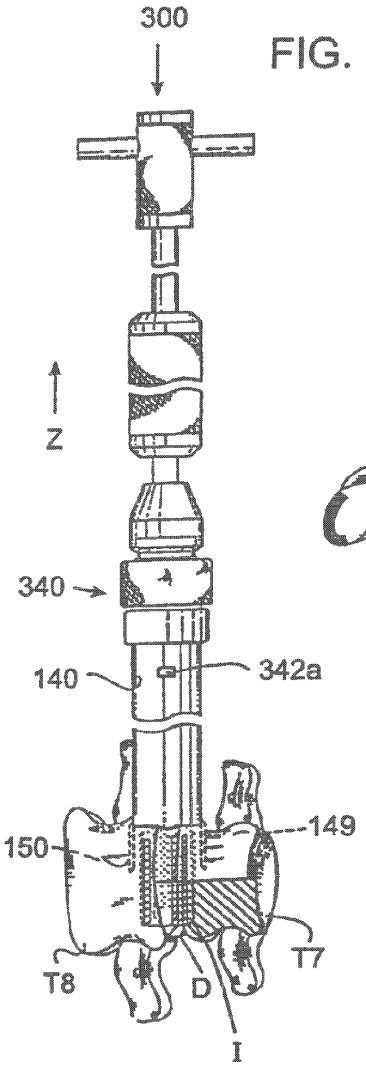


FIG. 22

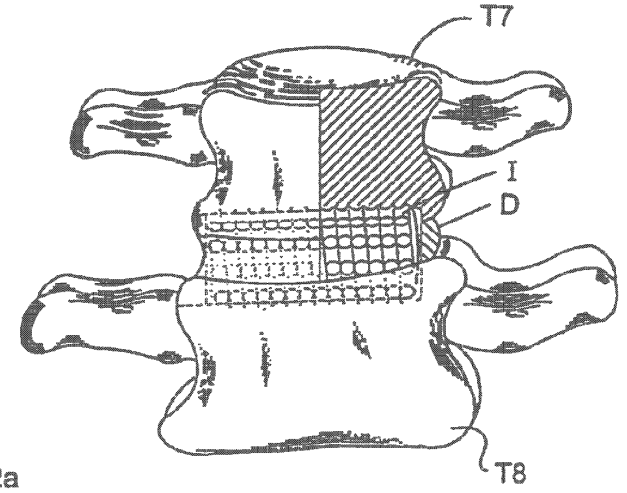


FIG. 23

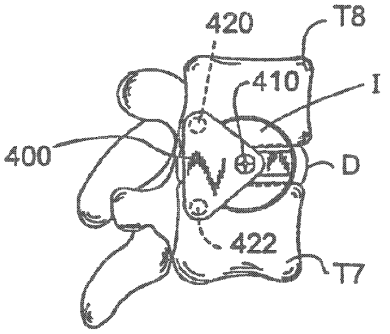


FIG. 24

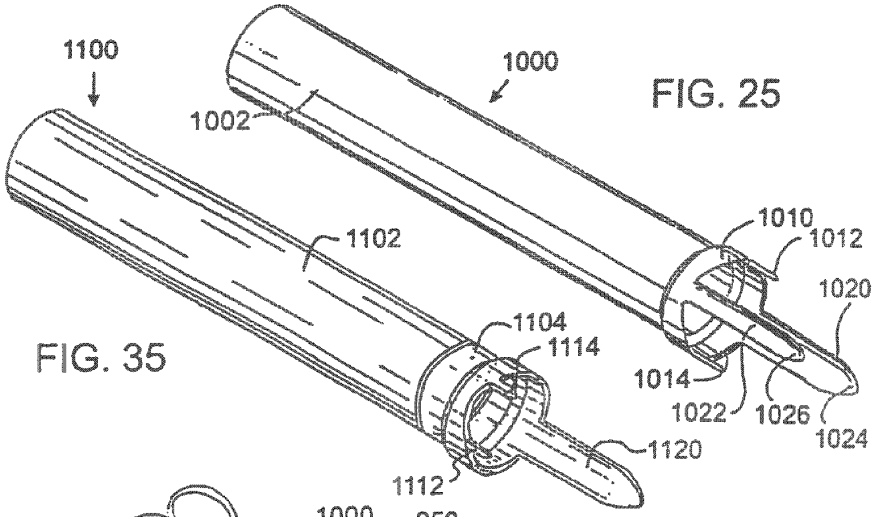


FIG. 35

FIG. 25

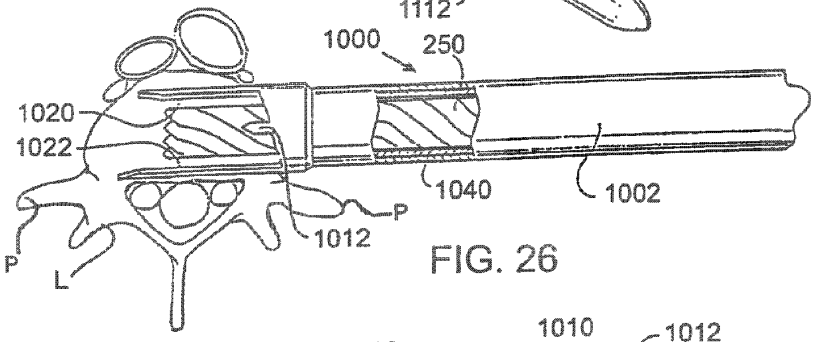


FIG. 26

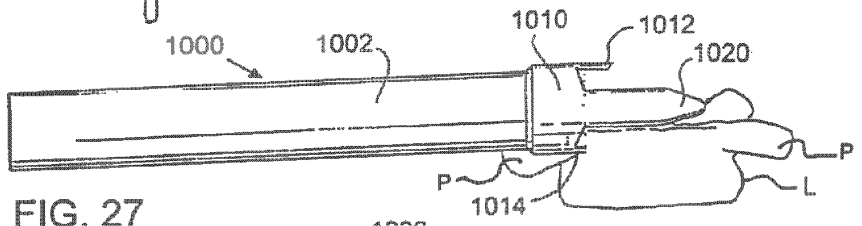


FIG. 27

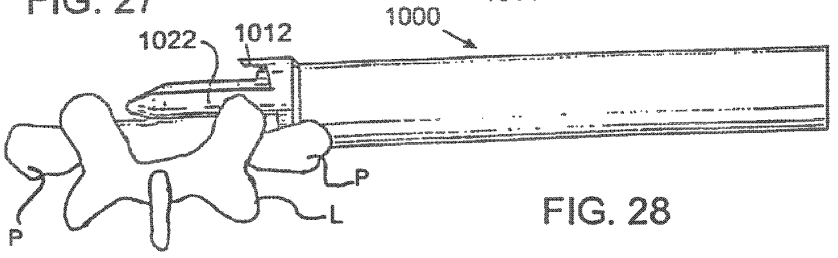
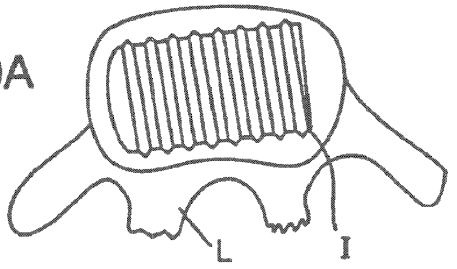


FIG. 28

FIG. 30A



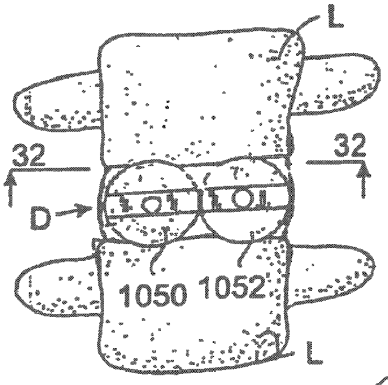


FIG. 31

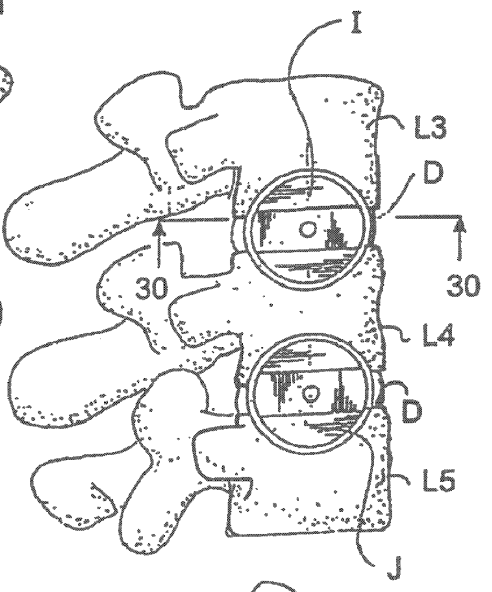


FIG. 29

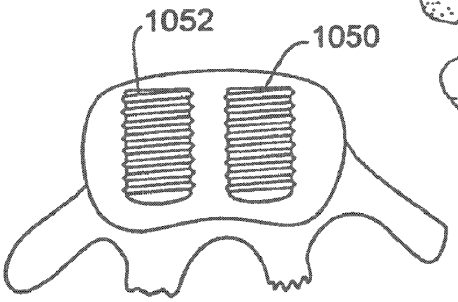


FIG. 32

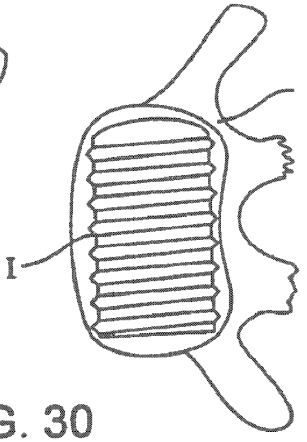


FIG. 30

FIG. 33

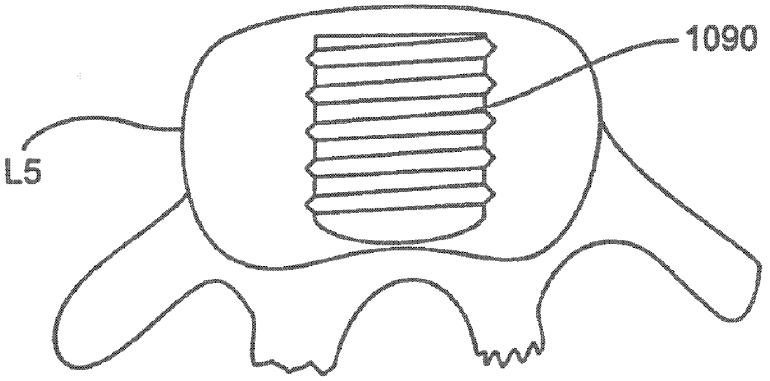
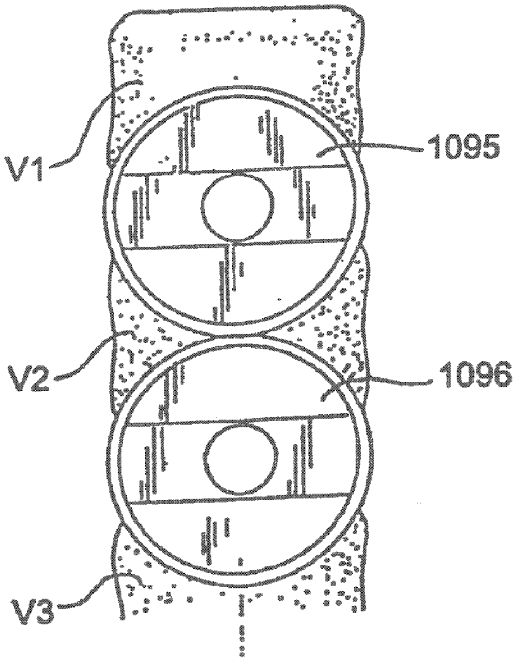


FIG. 34



METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

This application is a continuation of U.S. application Ser. No. 10/371,757, filed Feb. 21, 2003 (now U.S. Pat. No. 8,066,705); which is a continuation of U.S. application Ser. No. 08/480,461, filed Jun. 7, 1995 (now U.S. Pat. No. 7,491,205); which is a divisional of U.S. application Ser. No. 08/394,836, filed Feb. 27, 1995 (now U.S. Pat. No. 5,772,661); all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to instrumentation and methods of performing surgical procedures on the human thoracic and lumbar spine along the lateral aspect of the spine and from a true lateral or anterolateral approach, and specifically to the surgical correction of thoracic and lumbar disc disease and spinal deformities where concomitant fusion is desired.

2. Description the Prior Art

As regards the thoracic spine, it may be afflicted with a variety of ailments, some so severe as to require surgical intervention. A disc herniation may compress the spinal cord and/or nerve roots and cause pain, loss of function, and even complete paralysis of the legs with loss of bowel and bladder control. The correct treatment for such conditions is the removal of the offending discal tissue. However, this has proven both difficult and quite dangerous. When the discs of the thoracic spine are approached posteriorly (from behind) the spinal cord is in the way. To approach the same herniation anteriorly (from the front) requires the very formidable procedure of thoracotomy (cutting open the chest) and moving the heart and lungs out of the way.

procedures from a lateral approach to the spine (from the side) using fiber optic viewing instruments called thorascopes and numerous small surgical openings through the chest wall (portals) through which various surgical instruments, such as burrs, rongeurs and curettes, may be placed to remove these disc herniations while avoiding formal thoracotomy. Because the discs are very narrow in the thoracic spine and the surgeon is approaching the spine laterally, there is very little space in which to work as the disc is entered in order to get to the back of the disc space. Therefore, the amount of disc removal may be limited. In the alternative, the surgeon might remove the pedicle to gain access to the spinal canal risking further weakening of the already diseased area.

Sometimes, for a variety of reasons including the removal of disc material, the thoracic spine may become unstable (too much motion) at any given level. Historically, this has been treated by fusion, the joining together permanently of the unstable vertebrae via a bridge of bone so as to eliminate all motion at that location. Fusions about the thoracic spine have been performed either anteriorly or posteriorly, either procedure being a rather large surgical undertaking.

Stability of the spine is required for fusion to occur. For this reason, and for the purpose of correcting spinal deformity, it is often necessary to use hardware to rigidly internally fixate (stabilize) the spine. To date, the only benefit the use of the thorascope has provided in this regard is to allow the previous thoracotomy incision to be somewhat smaller.

So to date the following problems remain even utilizing the most recent technology as regards the surgical treatment of thoracic disc disease:

Firstly, the working space within the disc itself to access the herniation which is more posterior is quite limited.

Secondly, multiple or long incisions through the chest are still required.

Thirdly, when fusion is required a major surgical undertaking with its considerable risks is required.

Fourthly, the installation of hardware affixed to the spine still requires a thoracotomy, albeit a smaller one if visualization is assisted via the thorascope.

Fifthly, when, as is often the case, the patient requires all three, that is, discectomy (excision, in part or whole, of an intervertebral disc), fusion, and the application of hardware to the spine, those procedures are performed as serially (one after the other) combined surgical procedures with added surgical times, complications, morbidities, and mortalities.

As regards to the human lumbar spine, the treatment of discal disease with neural compression has generally been from a posterior (from behind) approach. This is sensible as the lumbar discs are generally quite large and it is only those protrusions occurring posteriorly which compress the neural elements which are themselves posterior to the discs. These posterior approaches have included both true posterior approaches and posterolateral approaches to the discs. Further, such approaches have been made via open incisions or through percutaneous stab wounds. In the latter case, instruments are inserted through the stab wounds and monitored by the use of radiographic imaging or the use of an endoscopic viewing device. While it is possible to also decompress a posterior disc herniation in the lumbar spine from an anterior approach (from the front) doing so requires the removal of a very substantial portion or all of the disc material in the front and mid portions of the disc thus leaving that disc incompetent and that spinal segment generally unstable. Therefore, such an anterior approach to the lumbar spine has been reserved for those instances where a fusion is to be performed in conjunction with, and following such a disc removal.

As regards to fusion, the application of bone or bone like substances between bones to induce bony bridging, such procedures have been performed outside the vertebral bodies and/or between the vertebral bodies. The latter being known as an interbody fusion. Such interbody fusions have been performed from posterior, posterolateral and anterior. The adjective applying specifically to the direction from which the bone grafts enter the intervertebral space. Interbody fusion from the posterior approach while still in use has been associated with significant complications generally related to the fact that the delicate dural sac and the spine nerves cover the back of the disc space and are thus clearly in harms way with such an approach. The posterolateral approach has generally been utilized as a compliment to percutaneous discectomy and has consisted of pushing tiny fragments of morsalized bone down through a tube and into the disc space.

Anterior interbody spinal fusion is performed from a straight anterior position as regards the path of entry of the fusion material into the intervertebral space. Such an anterior position is achieved in one of two ways. First, by a straight anterior approach which requires that the peritoneal cavity, which contains the intestines and other organs, be punctured twice, once through the front and once through the back on the way to the front of the spine; or secondly, by starting on the front of the abdomen off to one side and dissecting behind the peritoneal cavity on the way to the front of the spine. Regardless of which approach to the front of the spine is used, and apart from the obvious dangers related to the dense anatomy and vital structures in that area, there are at least two major problems specific to the anterior interbody fusion angle of implant insertion itself. First, generally at the L_4 L_5 disc, the

great iliac vessels bifurcate from the inferior vena cava lie in close apposition to, and, covering that disc space making fusion from the front both difficult and dangerous. Secondly, anterior fusions have generally been done by filling the disc space with bone or by drilling across the disc space and then filling those holes with cylindrical implants. As presently practiced, the preferred method of filling the disc space consists of placing a ring of allograft (bone not from the patient) femur into that disc space. An attempt to get good fill of the disc space places the sympathetic nerves along the sides of the disc at great risk. Alternatively, when the dowel technique is used, because of the short path from the front of the vertebrae to the back and because of the height of the disc as compared to the width of the spine, only a portion of the cylindrical implant or implants actually engages the vertebrae, thus, compromising the support provided to the vertebrae and the area of contact provided for the fusion to occur.

There is therefore, in regard to the lumbar spine, a need for a new method and means for achieving interbody fusion which method avoids the problems associated with all prior methods, and which have included, but are not limited to, nerve damage when performed posteriorly, or the need to mobilize the great vessels when performed anteriorly. Further, the size of the implants are limited by the dural sac posteriorly, and the width of the spine and the delicate vital structures therewith associated anteriorly. An improved method and means for interbody fusion should provide for optimal fill of the interspace without endangering the associated structures and allow for the optimal area of contact between the implant or implants and the vertebrae to be fused.

SUMMARY OF THE INVENTION

The present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side) and generally by a lateral or an anterolateral surgical approach, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

In the preferred embodiment, the instrumentation of the present invention comprises a guide pin, a distractor, an extended outer sleeve, an inner sleeve and drill adjustable for depth and with a depth limiting means. The distractor of the present invention is used for initially distracting (spacing apart) and realigning adjacent vertebrae of the spine and also functions as an alignment rod for inserting the extended outer sleeve. The distractor is placed at the affected disc space between adjacent vertebrae through a small incision in the body. For example, for surgery in the thoracic spine, a small incision in the chest cavity of the patient is made from a lateral approach to the thoracic spine. For surgery in the lumbar spine a small incision may be made in the abdominal wall of the patient. The insertion of the distractor may be guided by a guide pin previously inserted in the disc space and visually monitored for proper orientation and placement by the surgeon either indirectly through an image intensifier, or directly through a thorascope or by direct vision.

The extended outer sleeve in the preferred embodiment is a hollow tubular member having an extension member that is inserted in the disc space and is capable of distracting and aligning the two adjacent vertebrae from the lateral aspect of the spine. In the preferred embodiment, the extended outer sleeve has a pair of prongs for fixedly engaging the two adjacent vertebrae and further stabilizing the adjacent vertebrae. With the distractor in place in the affected disc space, the extended outer sleeve is placed over the distractor, and the distractor guides and aligns the insertion of the extended outer sleeve. As the extended outer sleeve is seated, the extension member becomes inserted in the disc space and the prongs engage the outside wall of the adjacent vertebrae. The distractor is then removed and the extended outer sleeve maintains the proper distraction and alignment of the adjacent vertebrae. The remainder of the surgical procedure consisting of disc removal, fusion, and rigid internal stabilization may all be performed via the dosed space within the extended outer sleeve. Alternatively, a convertible extended outer sleeve comprising a hollow tubular member that can be dissociated from its insertion end which remains engaged to the vertebrae to maintain distraction and alignment, may be used where it is desired to have direct visualization and access to the surgical site for at least a portion of the surgical procedure.

The drilling out and the subsequent removal of a rather significant mass of the disc itself may be curative in relieving a posterior disc herniation as the mass of tissue pushing from within the disc outward and posteriorly is thus removed. Further, the distractor in driving the vertebrae apart exerts significant tension on the walls of the disc which are pulled straight also tending to correct any disc herniation. Finally, since the hole drilled across the disc space is quite close to the posterior borders of the vertebrae, it makes the removal of any persisting posterior disc herniation quite simple. With the drill removed and the extended outer sleeve cleaned out by irrigation and suction, one can then place the endoscope directly down the outer sleeve and into the large space created by the removal of the disc, and in the preferred method, the adjacent vertebral bone, and then remove any remaining fragments of disc using conventional hand held instruments such as rongeurs and curettes under endoscopic visualization.

When it is desirable to remove posterior disc material, then a specialized modification of the extended outer sleeve having at its distal end a spine engaging portion comprising one anterior extension and posteriorly two prongs one each above and below the disc space may be used. Further, such an extended outer sleeve may be configured such that the great length of the hollow tubular portion of the extended outer sleeve is detachable, as by unscrewing, from the distal working end such that when uncoupled the distal end may remain in place maintaining distraction even after the hole is drilled and thus allowing the surgeon to work through that remaining portion of the extended outer sleeve and the space provided by the drilling to remove the posterior disc material under direct vision. For those instances where the surgeon has elected to access the spine through a more standard incision and is viewing the spine directly, the surgeon is then able to continue to operate through the distal spine engaging portion of the extended outer sleeve and still maintain the distraction and alignment of the vertebrae.

A spinal implant may then be inserted through the extended outer sleeve and into the hole in the adjacent vertebrae. The extended outer sleeve is removed once the spinal implant has been inserted. If the spinal implant being inserted has surface projections such as a thread, then an inner sleeve is inserted in the extended outer sleeve prior to drilling to accommodate the height of the projections or as in the case of a thread, the difference between the major and minor diameters of the implant.

To further stabilize the spinal implant, a staple alignment rod may be mechanically coupled to the spinal implant prior to the removal of the extended outer sleeve. The extended outer sleeve is then removed and a staple having spine engaging prongs is inserted via the alignment rod and is coupled to

the spinal implant. The alignment rod is removed and replaced with a locking screw to secure the staple to the spinal implant.

While the preferred method utilizing a cylindrical implant and involving the removal of some bone from each of the adjacent vertebrae in preparation for fusion has been described, it is understood that the distractor and sleeve could as well be rectangular and the drill supplemented with or replaced by a box chisel, or other chisel so as to produce a rectangular fusion site or similarly any of a variety of shapes. Further, it is understood that the outer sleeve could be dimensioned so as to confine the removal of the disc material, regardless of the means, to the area between the adjacent vertebrae rather than providing for the removal of the bone as well.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide instrumentation for performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide a method of performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine that is safer, more effective and faster than previously possible.

It is a further object of the present invention to provide instrumentation and method of inserting a spinal implant in a hole drilled across the disc space and into two adjacent vertebrae of the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide for a method and instrumentation for performing a thoracic discectomy, an interbody fusion, and rigid internal fixation of the spine through the chest cavity from a lateral approach and all as a single integrated procedure.

It is yet another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion from the lateral aspect of the spine.

it is further another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion and spinal canal decompression from the lateral aspect of the spine.

It is further still another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion, decompressive discectomy, and a rigid internal fixation of the spine and all as a single integrated surgical procedure.

It is further yet another object of the present invention to provide for a method and instrumentation to achieve discectomy, fusion and interbody stabilization of the lumbar without the need to mobilize the great vessels from the front of the vertebral bodies.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a rear perspective view of a segment of the thoracic spine with the guide pin of the present invention about to be inserted from a lateral approach to the thoracic spine into the disc space between two adjacent vertebrae.

FIG. **2** is a rear perspective view of a segment of the thoracic spine with the guide pin inserted in the disc space between two adjacent vertebrae and the distractor of the present invention about to be placed over the guide pin.

FIG. **3** is an enlarged front elevational view of a segment of the thoracic spine along line **3** of FIG. **2** having a portion of the top vertebrae removed and a portion of the disc removed with the guide pin, shown partially in hidden line, inserted from a lateral approach to the thoracic spine into the disc space.

FIG. **4** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the guide pin and distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine in the disc space.

FIG. **5** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine and seated in the disc space and the guide pin removed.

FIG. **6** is a rear perspective view of a segment of the thoracic spine having a distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and the extended outer sleeve of the present invention coupled to a driver cap and about to be placed over the distractor.

FIG. **7** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor and the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space.

FIG. **7**A is side perspective view of the extended outer sleeve of the present invention.

FIG. **8** is a rear perspective view of a portion of the thoracic spine with the extended outer sleeve fully seated over the distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and with the driver cap removed.

FIG. **9** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the adjacent vertebrae showing the distractor being removed by a distractor puller.

FIG. **10** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae.

FIG. **11** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the inner sleeve of the present invention being inserted into the extended outer sleeve.

FIG. **12** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the inner sleeve, shown in partial hidden line, inserted into the extended outer sleeve that is inserted from a lateral approach to the thoracic spine in the disc space and engages two adjacent vertebrae.

FIG. **13** is a side elevational view of a segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine in the disc space and engaging the two adjacent vertebrae with the inner sleeve and drill shown in an exploded view and partially in hidden line.

FIG. **14** is a cross sectional view along lines **14-14** of FIG. **13** of the drill, inner sleeve and extended outer sleeve.

FIG. **15** is a cross sectional view along lines **15-15** of FIG. **13** of the collar for limiting the drilling depth of the drill.

FIG. **16** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, the inner sleeve inserted in the extended outer sleeve, and the drill passing through the inner sleeve to create a hole across the disc space and into the adjacent vertebrae.

FIG. **17** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae illustrating a hole drilled across the disc space and into the adjacent vertebrae.

FIG. **18** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, an implant driver, and a spinal implant about to be inserted through the extended outer sleeve and into the hole drilled across the disc space and into the adjacent vertebrae.

FIG. **19** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and a spinal implant implanted in the hole drilled across the disc space and into two adjacent vertebrae.

FIG. **20** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and an extractor cap for removing the extended outer sleeve about to be coupled to the extended outer sleeve.

FIG. **21** is an enlarged partial sectional view of the extractor cap engaging the extended outer sleeve.

FIG. **22** is a front elevational view of the segment of the thoracic spine of FIG. **20** with the distractor puller coupled to the extractor cap shown removing the outer sleeve from the disc space and the adjacent vertebrae in the direction of the arrow.

FIG. **23** is an enlarged front elevational view of a segment of the thoracic spine having a portion of the top vertebrae removed and a portion of the disc space removed and a spinal implant implanted from a lateral approach to the thoracic spine in the hole drilled across the disc space and into the two adjacent vertebrae.

FIG. **24** is a front elevational view of a segment of the thoracic spine having a spinal implant implanted from a lateral approach to the thoracic spine into a hole drilled across the disc space and into the adjacent vertebrae with a spinal fixation device coupled to the spinal fusion implant and engaging the adjacent vertebrae to lock the spinal implant in place.

FIG. **25** is a side perspective view of an alternative embodiment of the extended outer sleeve of the present invention having a pair of extension members and a pair of prongs.

FIG. **26** is a top plan view of the extended outer sleeve of FIG. **25** shown in partial cutaway with an inner sleeve and a drill inserted within its interior and placed adjacent to a vertebra of the spine with the major vessels and the dural sac and spinal nerves proximate to the vertebra shown in cross section.

FIG. **27** is an anterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **26** shown inserted from the lateral approach and seated in the disc space and engaging the vertebra.

FIG. **28** is a posterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **25** shown inserted from the lateral approach of the spine and seated in the disc space and engaging the vertebra.

FIG. **29** is a side elevational view of a segment of the lumbar spine with a first spinal implant inserted from the lateral aspect into a hole drilled across a first disc space and into two adjacent vertebrae, and a second spinal implant inserted from the lateral aspect into a second hole drilled across a second disc space and into two adjacent vertebrae.

FIG. **30** is top sectional view along lines **30-30** of FIG. **29** showing the area of contact of the first spinal implant and the vertebra.

FIG. **30**A is a top sectional view similar to FIG. **30** showing the area of contact of a spinal implant inserted from slightly anterior (anterolateral) along the lateral aspect of the spine and oriented at least partially from side to side with respect to the vertebra.

FIG. **31** is an anterior elevational view of a segment of the lumbar spine with spinal cylindrical implants inserted from the anterior of the spine into holes drilled across the same disc space and into two adjacent vertebrae.

FIG. **32** is a top sectional view along lines **31-31** of FIG. **31** showing the area of contact of the two spinal implants and the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **33** is a top sectional view of a single implant having a diameter equal to the diameter of the implant of FIG. **30** showing the area of contact with the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **34** is a side elevational view of a segment of the spinal column with two spinal implants inserted from front to back at adjacent disc levels between three vertebrae.

FIG. **35** is a perspective side view of an alternative embodiment of the extended outer sleeve of the present invention having a removable distal end with a single extension member and a pair of prongs.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, a rear perspective view of a segment of the thoracic spine S is shown with a guide pin **30** about to be inserted from a lateral approach (through the lateral chest wall) to the thoracic spine S into the disc space D between two adjacent vertebrae, for example vertebrae T_7 and T_8. The guide pin **30** may first be used as radiological marker to confirm the correct disk level and instrument position, and then functions to align and guide the insertion of the instrumentation described below into the disc space D. The guide pin **30** is inserted through a small incision on the side of a patient's chest cavity perpendicular to the lateral aspect of the vertebrae T_7 and T_8 of the thoracic spine S. The guide pin **30** is made of a material appropriate for surgical use and comprises a shaft portion **40**, a tip **50** which may be pointed to facilitate insertion into the disc space D, and a distal end **60**. In the preferred embodiment, the guide pin has a diameter in the range of 1.5 mm to 5.0 mm, with 2.5 mm being the preferred diameter, and a length in the range of 200 mm to 800 mm, with 350 mm being the preferred length.

Referring to FIGS. **2** and **3**, the guide pin **30** is shown inserted from a lateral approach to the thoracic spine S and into the disc space D between adjacent vertebrae T_7 and T_8, with a substantial part of the shaft portion **40** of the guide pin **30** remaining external to the disc space D and functions as a guide post. The tip **50** of the guide pin **30** may penetrate the disc space D for a substantial part of the transverse width W of the vertebrae T_7 and T_8 such that at least a part of the shaft portion **40** is within the disc space D. The guide pin **30** is firmly embedded in the discal material present within the disc space D, but does not protrude through the opposite side of the disc space D to prevent any unwanted damage to that area. The guide pin **30** is placed in the disc space D so that it is parallel to the end plates of the vertebrae T_7 and T_8, and centered within the disc space D to bisect the disc space D along the transverse width W of the vertebrae T_7 and T_8. In

this manner, a substantial portion of the vertebrae T_7 and T_8 is present near the circumference of the guide pin **30** such that instruments having a diameter greater than the guide pin **30** may be inserted into the vertebrae T_7 and T_8 coaxial to the guide pin **30** without protruding from the vertebrae T_7 and T_8. Such instruments are guided and aligned during insertion by the guide pin **30** so that they are correctly oriented with respect to the vertebrae T_7 and T_8. The surgeon may monitor the correct orientation of the guide pin **30** within the disc space D indirectly with an image intensifier, or directly with a thorascope if one is being used.

Once inserted in the disc space D, the guide pin **30** functions as a guide post for a distractor **100** which is placed over the guide pin **30** and inserted in the disc space to distract the disc space D and align the adjacent vertebrae T_7 and T_8 by urging them apart. Circumstances permitting, the surgeon may elect to bypass the use of the guide pin **30** and insert the distractor **100** directly. The distractor **100** has a cylindrical barrel **106** that terminates at one end in a reduced diameter disc penetrating portion **102** that is essentially cylindrical, with a further reduced diameter, bullet-shaped front end **103** to facilitate insertion into the disc space D. The distractor **100** has a shoulder portion **104** where the penetrating portion **102** extends from barrel **106** and has a hallow longitudinal passageway **107** extending the entire length of the distractor **100** for receiving the guide pin **30**. The passageway **107** of the distractor **100** is open at both ends of the distractor **100** and has a diameter that is slightly greater than the diameter of the shaft portion **40** of guide pin **30**. The shaft portion **40** of the guide pin **30** may pass through the passageway **107** as the distractor **100** is placed coaxially over the guide pin **30**. In this manner, the distractor **100** can be guided and aligned by the guide pin **30** so that it is inserted into the disc space D coaxial to the guide pin **30** and is properly aligned with respect to the vertebrae T_7 and T_8. Once the distractor **100** is properly placed within the disc space D, the guide pin **30** may be removed from the disc space D through the passageway **107** of the distractor **100**.

The appropriate placement of distractor **100** in the disc space D may be determined visually by the surgeon by the use of a thorascope and or by the use of radiographic, fluoroscopic, or similar procedures, such as utilizing an image intensifier, all of which allow the surgeon to determine the correct orientation and placement of the guide pin **30** and distractor **100** within the disc space D. The correct orientation and placement of the distractor **100** is important to the success of the method of the present invention, as the purpose of the distractor **100** is to space part and align the vertebrae T_7 and T_8 and to guide the insertion into the disc space D of the extended outer sleeve **140** described in detail below. As the diameter of the distracter **100** is almost the same as the inner diameter of the extended outer sleeve **140** and is the same as the spinal implant I, also described in detail below, the surgeon can use x-rays to determine whether the distractor **100** is properly oriented with respect to the adjacent vertebrae T_7 and T_8, such that any subsequent drilling through the extended outer sleeve **140** and insertion of spinal implant I will be correctly oriented with respect to the vertebrae T_7 and T_8. Such a precaution will permit the surgeon to correct any misplacement of the distractor **100** before any irreversible drilling or implant insertion has occurred.

The penetrating portion **102** of the distractor **100** may be of various diameters and lengths, the preferred length being less than the known transverse width W (side to side) of the vertebrae T_7 and T_8. This combined with the circumferential shoulder portion **104** of the distractor **100**, which is too large to fit within the disc space D, protects against the danger of overpenetration. The barrel **106** of the distractor **100** may have at its distal end a recessed portion **108** below the crown **110** which allows for the distractor **100** to be engaged by an extractor unit shown in FIG. **9**.

In the preferred embodiment of the distractor **100**, the barrel **106** has a diameter in the range of 10 mm to 30 mm, with 20 mm being the preferred diameter, and the penetrating portion **102** has a diameter in the range of 3 mm to 10 mm, with 6 mm being the preferred diameter.

Referring to FIGS. **4** and **5**, once the distractor **100** is inserted into the disc space D, the penetrating portion **102** of the distractor **100** distracts the vertebrae T_7 and T_8 apart, such that the vertebrae T_7 and T_8 to either side of the penetrating portion **102** are forced into full congruence and thus become parallel, not only to the penetrating portion **102**, but to each other. Because of the forced opposition of the vertebrae T_7 and T_8 to the penetrating portion **102** the distractor **100** will then come to lie absolutely perpendicular to the plane P of the lateral aspect of the thoracic spine S and absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Referring to FIGS. **6**, **7** and **7**A, the distractor **100** now serves as both a centering post and an alignment rod for the extended outer sleeve **140** which is fitted over the distractor **100** and inserted into the disc space D. As shown in FIG. **7**A, the extended outer sleeve **140** is a hollow tubular member made of material appropriate for surgical use and preferably metal, and has an inner diameter sufficiently sized to receive the distractor **100**. The inner diameter of the extended outer sleeve **140** closely matches the outer diameter of the distractor **100**, so that a dose fit is achieved and the extended outer sleeve **140** is precisely guided by the distractor **100**. The extended outer sleeve **140** has at its distal end **146** an extension member **148** and two prongs **149** and **150** sufficiently spaced apart to penetrate and hold fixed the two adjacent vertebrae T_7 and T_8. The extension member **148** is essentially a continuation of the extended outer sleeve **140** and the prongs **149** and **150** are offset from the extended outer sleeve **140** or can also be a continuation of the extended outer sleeve **140** like extension member **148**. The prongs **149** and **150** may have sharp insertion edges **152** and **154** to facilitate insertion into the vertebrae T_7 and T_8.

Where the surgery is for a disc herniation, the extension member **148** of the extended outer sleeve **140** located anteriorly is used without a second extension member posteriorly, as the use of the two prongs **149** and **150** in conjunction with the anterior extension member **148** makes it possible to operate through the extended outer sleeve **140** posteriorly, without obstruction and with good visibility when an endoscope is used such that any remaining disc herniation may be removed. The extension member **148** of the extended outer sleeve **140** provides a protective barrier to the structures lying beyond it.

However, if the surgery is not for a disc herniation, but for example, for stabilization of the spine, then the extended outer sleeve may have both an anterior extension member **148** and a corresponding posterior extension member with or without prongs, such as the extended outer sleeve **1100** shown in FIG. **35** and described in greater detail below.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8, as the extension member **148** is being inserted from the lateral aspect of the thoracic spine S. Without the extension member **148**, in order to maintain the proper distraction of the adjacent vertebrae T_7 and T_8, it would be necessary to place a surgical instrument, such as a second distractor (not shown) on the

opposite side of the vertebrae T_7 and T_8. This would require a second incision in the opposite side of the patient's chest cavity for insertion of the required surgical instruments. Further, as it is desired to insert an implant of the maximum possible length across the transverse width W of the vertebrae T_7 and T_8, the presence of any instrumentation at the opposite end of the vertebrae T_7 and T_8, would interfere with the insertion of such an implant. For example, the second distractor on the opposite side of the vertebrae T_7 and T_8 would be in the way of a drill used to create a hole across the transverse width W of the vertebrae T_7 and T_8, since the drilled opening would overlap the second distractor. Therefore, the extension member **148** solves the problem of maintaining an even distraction of the two adjacent vertebrae T_7 and T_8 across their transverse width W from only one side of the thoracic spine S, allowing for the unimpeded insertion of instruments and/or implants. While in the preferred embodiment, the extended outer sleeve **140** has an extension member **148**, it is also possible to have an extended outer sleeve without any extension members and instead, having prongs of sufficient length that engage the bone of the adjacent vertebrae to maintain the distraction and alignment of the adjacent vertebrae created by the distractor **100**. However, the use of such an extended outer sleeve capable of holding, but not of obtaining, the desired intervertebral distraction and alignment would require the use of a distractor prior to its insertion as earlier described herein.

In the preferred embodiment of the extended outer sleeve **140**, a single extension member **148** is present and oriented anteriorly to protect the major vessels located to the anterior aspect of the thoracic spine S. The extended outer sleeve **140** has no extension member near the posterior aspect the spine as it is often necessary to access the spinal canal in order to remove any diseased discal material. In the special circumstances where only vertebral fusion is desired, the extended outer sleeve **140** may have a second extension member (not shown) identical to the extension member **148** positioned diametrically opposite the extension member **148** in order to protect the spinal canal, and in such instance may or may not have the bone penetrating prongs **149** and **150**.

The extension member **148** of the extended outer sleeve **140** has a height that is generally approximately equal to the diameter of the penetrating portion **102** of the distractor **100**, such that the extension member **148** is capable of maintaining the spacing created by the insertion of the distractor **100** between the adjacent vertebrae T_7 and T_8 which is generally the restoration to normal of the disc space D. The extension member **148** is tapered at its leading edge **151** to facilitate insertion into the disc space D and is positioned approximately 120 degrees from each of the two prongs **149** and **150**. The extension member **148** of the extended outer sleeve **140** works in conjunction with the prongs **149** and **150** which engage the vertebrae T_7 and T_8, respectively, to maintain the distraction and alignment of the vertebrae T_7 and T_8. Further, the prongs **149** and **150** not only hold the vertebrae T_7 and T_8 apart, but during drilling also help to hold them together so as to resist them moving apart.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length that is less than the transverse width W of the vertebrae T_7 and T_8. The extension member **148** needs to be relatively long because it must maintain distraction of the adjacent vertebrae T_7 and T_8 when placed across the transverse width W of the vertebrae T_7 and T_8. Therefore, if the extension member **148** is shorter than one half the transverse width W of the vertebrae T_7 and T_8, it may not be capable, of distracting and aligning the vertebrae T_7 and T_8, and a second distractor would be required as described above, to achieve the correct distraction and alignment of the vertebrae T_7 and T_8.

In the preferred embodiment, the extended outer sleeve **140** has an outer diameter in the range of 12 mm to 34 mm, with 24 mm being the preferred outer diameter, and an inner diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred inner diameter of the extended sleeve **140**.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length in the range of 14 mm to 30 mm, with 24 mm being the preferred length, and a height in the range of 3 mm to 10 mm, with 6 mm being the preferred height. In the preferred embodiment, the prongs **149** and **150** of the extension member **140** have a length in the range of 6 mm to 20 mm, with 14 mm being the preferred length and a diameter in the range of 2 mm to 3 mm, with 2 mm being the preferred diameter of the prongs **149** and **150**.

Referring specifically to FIG. **6**, coupled to the proximal end **157** of the extended outer sleeve **140** is a driver cap **160** in the form of an impaction cap which has at its far end a flat, closed-back surface **162** and at its other end a broad, circular opening. The driver cap **160** is used for driving the extended outer sleeve **140** toward the vertebrae T_7 and T_8 and fits over both the extended outer sleeve **140** and the distractor **100**. An impaction force, such as a mallet blow, is applied to surface **162** of the driver cap **160** to advance the extended outer sleeve **140**. That force is transmitted to the extended outer sleeve **140** via its proximal end **157**, seating the prongs **149** and **150** of the extended outer sleeve **140** into the vertebrae T_7 and T_6 and inserting the extension member **148** into the disc space D. As the extended outer sleeve **140** is advanced forward, the crown **110** of the distractor **100** is allowed to protrude within the driver cap **160** unobstructed until it contacts the interior of the driver cap **160**, such that further taps of the mallet will not further advance the extended outer sleeve **140**. Any further motion is resisted by the flat shoulder portion **104** of the distractor **100** abutting the hard lateral outer surfaces of the adjacent vertebrae T_7 and T_8. The flat, planar area **156** of the distal end **146** of extended outer sleeve **140** serves to resist the further insertion of the extension member **148** into the disc space D and to resist further insertion of the prongs **149** and **150** into the vertebrae T_7 and T_8. In this way, the extended outer sleeve **140** is safely and assuredly inserted to its optimal depth, and no further, and rigidly secures the two adjacent vertebrae T_7 and T_8 as shown in FIG. **7**.

Referring to FIGS. **8** and **9**, the driver cap **160** is then removed and the crown **110** and the recessed portion **108** of the distractor **100** protrude from the proximal end **157** of the extended outer sleeve **140**. The distractor **100** may now be removed from within the extended outer sleeve **140** since the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8. The extended outer sleeve **140** is held secure by the extension member **148** inserted within the disc space D and by the prongs **149** and **150** engaging the vertebrae T_7 and T_8.

A distractor puller **200** is utilized to remove the distractor **100** in the direction of arrow Y from within the disc space D leaving the extended outer sleeve **140** in place. The distractor puller **200** has front portion **202**, a mid portion **204**, and a back handle portion **206**. The front portion **202** of the distractor puller **200**, is connected to one end of shaft **210** which at its far end is connected to the back handle portion **206**. The distractor puller **200** is described in detail in copending U.S. application Ser. No. 08/074,781, entitled APPARATUS AND METHOD FOR INSERTING SPINAL IMPLANT, and is incorporated herein by reference. The socket-like front portion **202** of the distractor puller **200** engages the circumferential recessed portion **108** of the distractor **100**.

A cylindrical and freely movable weight **216** is fitted around shaft **210** between the front portion **202** and the rear handle portion **206** of the distractor puller **200** so as to form a slap hammer. The weight **216** of the distractor puller **200** is gently and repeatedly slid along the shaft **210** and driven rearwardly against flat surface **228** of the rear handle portion **206** to transmit a rearward vector force to front portion **202** and to the distractor **100** to which it is engaged. In this manner, the distractor **100** is removed from within the disc space D and out of the extended outer sleeve **140** without disturbing it.

Referring to FIG. **10**, once the distractor **100** has been completely removed from within the extended outer sleeve **140** and from within the disc space D, the extension member **148** remains within the disc space D and the prongs **149** and **150** rigidly maintain the appropriate distraction and the relative position of the adjacent vertebrae T_7 and T_8. The remainder of the procedure occurs entirely through the extended outer sleeve **140** and the space therein is sealed off from any of the organs of the chest.

Referring to FIGS. **11** and **12**, since the extended outer sleeve **140** is of a fixed length and rigid, the fiat rearward surface **172** of the distal end **146** may be used as a stop to the advancement of any instruments placed through the extended outer sleeve **140**, thus protecting against accidental overpenetration. Further, the extended outer sleeve **140** assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the adjacent vertebrae T_7 and T_8.

Where it is desirable to drill a hole smaller in diameter than the spinal implant to be inserted, such as in the case where the spinal implant is threaded, an inner sleeve **242** which functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of the spinal implant, is inserted in the proximal end **158** of the extended outer sleeve **140**. The inner sleeve **242** is a hollow tubular member comprising a barrel portion **243** and a cuff portion **244** having a greater outer diameter than the barrel portion **243**. The cuff portion **244** of the inner sleeve **242** seats against the flat rearward surface **172** of the extended outer sleeve **140** to prevent further insertion of the inner sleeve **242**. The distal end **246** of the inner sleeve **242** extends towards but does not impact the lateral aspect of the adjacent vertebrae T_7 and T_8 in the interior of the extended outer sleeve **140** when fully seated. The barrel portion **243** of the inner sleeve **242** has an outer diameter that fits within the inner diameter of the extended outer sleeve **140**. In the preferred embodiment, the barrel portion **243** of the inner sleeve **242** has an outside diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred outer diameter, and a wall thickness in the range of 0.5 mm to 3 mm, with approximately 0.75 to 1.5 mm being the preferred thickness.

Referring to FIGS. **13-15**, once the inner sleeve **242** is seated within the extended outer sleeve **140**, a drill **250** connected to a handle **260** or to a drill motor (not shown), is introduced through the aperture in the proximal end **248** of the inner sleeve **242** and utilized to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8. The drill **250** reams out arcs of bone which it engages from the adjacent vertebrae T_7 and T_8, as well as any discal material within its path down to its predetermined and limited depth. It is appreciated that if an inner sleeve **242** is not used, the drill **250** may be placed directly into the extended outer sleeve **140** to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8.

The drill shaft of drill **250** comprises an upper portion **252**, a central recessed portion **254** of a smaller diameter and a lower cutting portion **256**. The drill **250** has a narrow engagement portion **258**, which allows it to be affixed to a driving mechanism which may be either a manual unit such as, handle **260**, or a power unit such as an electric drill motor. The upper portion **252** has a plurality of grooves **261** for engaging a circumferential collar **262** of an increased diameter which serves to limit the depth of penetration of the drill **250** and may be fixed, or lockably adjustable.

Referring to FIG. **15**, a cross sectional view of the circumferential collar **262** is shown engaging the upper portion **252** of the shaft of drill **250**. The collar **262** comprises diametrically opposite first and second flanges **264** and **266**. The first and second flanges **264** and **266** are pivotably attached to the collar **262** by first and second pins **268** and **270** and spring biased by first and second spring **272** and **274**. The first and second flanges **264** and **266** of the collar **262** are contoured to correspond to the curvature of the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** engage one of the grooves **261** when in the full biased position as shown in FIG. **15**. To disengage the grooves **261**, the first and second **264** and **266** are compressed together by the surgeon such that the first and second springs **272** and **274** are compressed and the first and second flanges **264** and **266** pivot away from the upper portion **252** of the shaft, such that the collar **262** can slide along the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** of the collar **262** are oriented opposite each other and need to be compressed together in order to disengage the grooves **261**. The compression of one of the flanges **264** and **266** alone will not disengage the collar **262** from the grooves **261**. In this manner, collar **262** can not become accidentally disengaged during the rotation of the drill **250**.

While it is believed that this mechanism is entirely novel, it is appreciated that various mechanisms to lockably adjust drills are well-known to those skilled in the art. Such mechanisms include, but are not limited to, the use of collets, threaded shafts with lock nuts, and flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them.

Referring to FIGS. **13** and **14**, in the preferred embodiment, the forward cutting edge **280** of drill **250** is a four cutting edge end mill modification of a large fluted drill design. The cutting portion **256** of the drill **250** resembles an end cutting mill which may contain any workable number of cutting surfaces, but preferably four or more, that are relatively shallow such that the advancement of the drill **250** occurs more slowly. The cutting portion **256** of the drill **250** may be of a different diameter depending on the type of spinal implant that is being inserted. If the spinal implant being inserted is threaded, the outside diameter of the cutting portion **256** of the drill **250** would generally correspond to the minor diameter of the threaded implant. The inner sleeve **242** has an inner diameter slightly greater than the minor diameter of a threaded implant and its outer diameter is slightly smaller than the inside diameter of the extended outer sleeve **140** which has the same outer diameter as the major diameter (with threads) of the threaded implant. If the implant is not threaded, the outside diameter of the drill **250** corresponds to the inside diameter of the extended outer sleeve **140** such that a hole the maximum diameter of the extended outer sleeve may be drilled.

The inner sleeve **242** serves many functions. First, it provides an intimate drill guide for drill **250** in the event a smaller diameter hole is to be drilled than that of the inside diameter of the extended outer sleeve **140**. Second, since the inner sleeve **242** guides the drill **250**, it allows for the extended outer sleeve **140** to have an internal diameter large enough to

admit a threaded implant, which is larger in diameter than the outer diameter of the drill **240**.

If a larger extended outer sleeve **140** were utilized absent the inner sleeve **242**, then the drill **250** would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae T_7 and T_8. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the drill **250** must be equally centered within the disc space, parallel the endplates, and perpendicular to the long axis of the spine dissecting the disc space D.

A further purpose of the inner sleeve **242** is that it may be removed simultaneously with the drill **250**, thereby trapping the debris, both cartilaginous and bony, generated during the drilling procedure. The debris is guided rearward by the large flutes **251** of the lower cutting portion **256** and is collected around the central recessed portion **254** and then contained and between the recessed portion **254** and the inner wall of the inner sleeve **242**. Thus, by removing the drill **250** in conjunction with the inner sleeve **242**, much of the debris generated by the drilling procedure is safely removed from the drilling site.

Referring to FIG. **17**, once the drill **250** and the inner sleeve **242** are removed from the extended outer sleeve **140** a cylindrical hole **290** remains across the disc space D and into the two adjacent vertebrae T_7 and T_8. The cylindrical hole **290** is oriented across the transverse width W of the vertebrae T_7 and T_8, in which an implant of appropriate diameter is to be implanted. The proper distraction and orientation of the two adjacent vertebrae T_7 and T_8 is maintained by the extension member **148** and the prongs **149** and **150** of the extended outer sleeve **140**.

The cylindrical hole **290** may then be irrigated and vacuumed through the extended outer sleeve **140** to remove any remaining debris from the drilling, if necessary, a thrombin soaked sponge may be inserted through the extended outer sleeve **140** and into the cylindrical hole **290** to coagulate any bleeding. The thrombin soaked sponge is then removed and the surgeon utilizing an endoscope then visually inspects the cylindrical hole **290** for any remaining discal material, and removes any such material requiring such removal with a surgical instrument such as a curette or rongeur.

Referring to FIG. **18**, with the extended outer sleeve **140** still in place, the surgical site is now fully prepared to receive a spinal implant I for fusion of the vertebrae T_7 and T_8. The spinal implant I may be coated with, and/or made of, and/or loaded with substances consistent with bony fusion which may promote bone growth and/or fusion prior to being implanted. Once the spinal implant I has been prepared for implantation, a driver instrument, such as driver **300** may be used to either insert or to remove spinal implant I. Driver **300** has at its distal end **302**, a rectangular protrusion **304**, which intimately engages the complimentary rectangular slot in the rear of implant I. Extending from the rectangular protrusion **304** is threaded portion **306**, which extends as a rod through hollow shaft **308** and hollow barrel portion **310** to knob **312** where it can be rotationally controlled. Threaded portion **306** screws into a threaded aperture in the spinal implant I and binding them together such that driver **300** can be rotated via paired and diametrically opposed extending arms **314** and **316** and in either direction while maintaining contact with the spinal implant I.

Affixed to the driver **300**, the spinal implant I is then introduced through the extended outer sleeve **140** and if the spinal implant I is threaded, screwed into the cylindrical hole **290** between the two vertebrae T_7 and T_8 until such time as the leading edge of the implant cap **318** reaches the depth of the cylindrical hole **290** at which time its forward motion is impeded by the bone lying before it which had not been drilled out. This allows for a progressive feel to the surgeon as the spinal implant I is inserted into place. It is appreciated that if the spinal implant I is not threaded, instead of being screwed into hole **290**, it may be linearly advanced into hole **290** by pushing the driver **300** toward the hole **290**.

The terminal resistance to further seating provides significant tactile feedback to the surgeon. Visual monitoring of the depth of insertion of the spinal implant I is provided to the surgeon by observing the progressive approximation of the forward surface **320**, of barrel portion **310**, as it approaches the rearward facing surface **172** of extended outer sleeve **140** and/or by the use of an image intensifier. As a final safety mechanism, when the full depth of insertion has been achieved, forward surface **320** of instrument **350** will abut surface **172** of the extended outer sleeve **140**, prohibiting any further installation of the implant. Once the spinal implant has been fully installed, the driver **300** is dissociated from the implant by turning knob **312** in a counterclockwise direction. The driver **300** is then withdrawn from the extended outer sleeve **140**.

Referring to FIG. **19**, the spinal implant I is shown fully installed to the determined depth in the cylindrical hole **290** drilled across the disc space D and into the adjacent vertebrae T_7 and T_8. The spinal implant I shown comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, preferably titanium. However, it is appreciated that other implants, cylindrical or partially cylindrical, or of a variety of shapes, and with or without threads or surface roughenings may be used with the instrumentation and method of the present invention.

Referring to FIGS. **20** and **21**, an extractor cap **340** for removing the extended outer sleeve **140** is shown about to be coupled to the extended outer sleeve **140**. The extractor cap **340** engages the proximal end **157** of the extended outer sleeve **140** by spring tabs **342***a* and **342***b* on either side of extractor cap **340** which snap-fit into openings **344***a* and **344***b* on either side of the extended outer sleeve **140** to lock in place. The extractor cap **340** has a top **346** that is similar in structure to the proximal end of the distractor **100**, having a recess portion **350** and a crown portion **352**.

Referring to FIG. **22**, once the extractor cap **340** is coupled to the extended outer sleeve **140**, the distractor puller **200** is coupled to the top **346** of extractor cap **340** to remove the extended outer sleeve **140** from the disc space D and from the adjacent vertebrae T_7 and T_8 in the direction of the arrow Z.

Referring to FIG. **23**, once the extended outer sleeve **140** has been removed, the spinal implant I remains implanted within the cylindrical hole **290** drilled across the disc space D and the implant engages the two adjacent vertebrae T_7 and T_8.

Referring to FIG. **24**, the spinal implant I may be further stabilized with use of a spinal fixation device **400** such as the staple disclosed in copending U.S. application Ser. No. 08/219,626 entitled APPARATUS, INSTRUMENTATION AND METHOD FOR SPINAL FIXATION, which is incorporated herein by reference. The spinal fixation device **400** is coupled to the spinal implant I with a locking screw **416** and engages the vertebrae T_7 and T_8 via prongs **420** and **422**. The spinal fixation device **400** functions to stabilize the spinal implant I and prevent any unwanted excursion of the spinal implant I during the spinal fusion process. It is appreciated that prior to removal of the extended outer sleeve **140**, a centering post (not shown) may be inserted through the extended outer sleeve **140** and attached to the threaded opening in the back of the spinal implant I. The extended outer

sleeve **140** is then removed and the centering post functions as guide to align the spinal fixation device **400** as it is being driven into the vertebrae T_7 and T_8 as described in detail in the copending application referenced immediately above.

In the above description in regard to the thoracic spine, the surgical procedure has been described as being performed through a hollow tube (extended outer sleeve **140**) and with the aid of a thorascope. It is appreciated that there may be circumstances where the surgeon will elect to perform the surgical procedure through an incision, such as a thoracotomy, where direct visualization of the surgical site is possible obviating the need for the thorascope but without diminishing the teaching of the method of the present invention. In such cases, a modification of the extended outer sleeve **140**, such as the extended outer sleeve **1100** shown in FIG. **35** and described in detail below, having a detachable distal end may be beneficially utilized by the surgeon. In this manner, the surgeon has direct visualization of the surgical site while the proper distraction and alignment of the adjacent vertebrae is maintained throughout the procedure by the distal end of the extended outer sleeve.

While the present invention has been described in association with the insertion of a threaded spinal implant, it is recognized that other forms of implants may be used with the present method. For example, dowels, made from bone, coral or artificial materials, knurled or irregularly shaped cylinders or spheres, partial cylinders or any other shaped implants that can be introduced through the extended outer sleeve **140**, which itself need not be cylindrical may be used.

When such implants are used, it is appreciated that the steps of the method of the present invention described above may be reduced. For example, once the extended outer sleeve **140** has been seated such that the extension portion **148** is inserted in the disc space D and the prongs **149** and **150** engage the adjacent vertebrae, the step of inserting the inner sleeve **242** may be omitted and a drill having a diameter approximating that of the inner diameter of the extended outer sleeve **140** may be used to drill a hole the size of the inner diameter of the extended outer sleeve **140** across the disc space D and into the adjacent vertebrae. Once the drill has been removed, any remaining discal material or debris may be removed by irrigating and vacuuming the hole, and an implant such as a bone dowel or an implant without threads, may be linearly advanced through the extended outer sleeve **140** and implanted into the hole. The extended outer sleeve **140** is then removed in the same manner described above. Where the implant shape is generally not circular, an appropriately shaped chisel may be used by itself or in conjunction with a drill to prepare an opening for the fusion implant that is other than round.

It is further appreciated that it is also within the scope of the present invention to provide a method and instrumentation for the insertion of a spinal implant into the disc space between two adjacent vertebrae, without the drilling away of significant bone from the vertebrae. Such implants may have a height corresponding to the height of a disc space D and may be pushed into the disc space D when distracted once the disc space has been cleaned out. This type of implant would preferably have in part a rectangular cross section and an extended outer sleeve used for the insertion of such implants would have a corresponding cross section and shape. Further, it is appreciated that the extended outer sleeve and inner sleeve of the present invention may have any shape or size corresponding to the shape and size of the implant to be inserted without departing from the scope of the present invention.

While the above description has been directed to the thoracic spine, the method and instrumentation of the present invention may also be utilized in the lumbar spine. In the preferred method, the surgeon makes a small incision in the abdominal wall and gently dissects his way retroperitoneal to reach the lateral aspect of the spine. As with the thoracopic method described above, the surgeon may use an endoscope within and/or outside of the extended outer sleeve to facilitate the surgery, and thereby require an incision barely larger than the diameter of the extended outer sleeve which itself is not much larger than the implant.

Referring to FIG. **25**, an extended outer sleeve **1000** for use with the lateral method in the lumbar spine is shown. The extended outer sleeve **1000** is similar to the extended outer sleeve **140** described above and comprises a hollow tubular member **1002** having a distal end **1010** which is contoured to hug the vertebrae, for example L_4 and L_5. The extended outer sleeve **1000** has anterior and posterior extension members **1020** and **1022**, each having different heights, that are opposed 180 degrees from each other. Also extending from the distal end **1010** may be prongs **1012** and **1014**, similar to prongs **149** and **150** described above, for engaging the bone of the adjacent vertebrae L_4 and L_5. The extension members **1020** and **1022** are tapered at their leading edges **1024** and **1026** respectively, to facilitate insertion.

As shown in FIGS. **26-28**, the extended outer sleeve **1000** is designed to be used in approaching the lumbar spine laterally from either side of the spinal column. The extended outer sleeve **1000** by means of its extended portions **1020** and **1022** is capable of correcting those spinal deformities, such as scoliosis or any abnormality of kyphosis or lordosis, occurring specifically from a deformity of the disc. For example, in order to restore lordosis in the lumbar spine, the anterior extension member **1020** is placed anteriorly between the adjacent vertebrae L_4 and L_5 and the posterior extension member **1022**, having a lesser height than the extension member **1020**, is placed posteriorly. The greater height of the extension member **1020** relative to the extension member **1022** maintains the anterior portions of the vertebrae L_4 and L_5 spaced apart at a greater distance than the posterior portions of the vertebrae L_4 and L_5 producing an angular relationship between the bodies as would exist with naturally occurring physiologic lordosis. Once restored, lordosis is maintained throughout the surgical procedure.

Scoliosis refers to an abnormal curving of the spine when viewed from straight ahead or behind. Since the extension members **1020** and **1022** may be of a specific and constant height throughout their entire lengths, both sides of the disc space D are lifted to exactly the same height, thus eliminating any side to side angular deformity occurring through that disc space.

Referring specifically to FIG. **26**, it can be appreciated that the posterior extension member **1022** effectively prevents any injury to the dural sac and neural elements, while the anterior extension member **1020** in a similar fashion, protects the great blood vessels including the aorta, vena cave and the iliac arteries and veins. As the extended outer sleeve **1000** of the present invention is quite stable once inserted, the preferred embodiment is shown as having only two prongs **1012** and **1014**, one each to engage each of the adjacent vertebrae L_4 and L_5. It is, however, understood that the extended outer sleeve **1000** may have more or less prongs or none at all. The distal end **1010** of the tubular member **1002** is contoured adjacent the origin of the anterior and posterior extended members **1020** and **1022** so as to assure an intimate fit between the tubular member **1002** and the vertebrae L_4 and L_5 adjacent the disc space D to which it is opposed, and for the purpose of confining the surgery to within the extended outer sleeve **1000** and excluding the adjacent soft tissues from

potential injury. In the preferred embodiment, the distal end of the tubular member **1002** and the anterior and posterior extended members **1020** and **1022** themselves have been reinforced, that is are thicker than the adjacent tubular member **1002** itself so as to provide for increased support within the lumbar spine.

Referring still to FIG. **26**, the extended outer sleeve **1000** engages the spine laterally, although the surgical approach in reaching the spine may be from an anterior, lateral, or anterior-lateral incision on the outside of the body, and is hereinafter referred to as the "Lateral Method". The "Lateral Method" involves the insertion of a distractor, such as, but not limited to the distractor **100** described above into the lateral aspect of the spine, and generally from a side to side direction although said direction could be slightly from anterolateral to slightly posterolateral (diagonalized from the transverse axis) without departing from the teaching of the method of the present invention to distract the adjacent vertebrae, in this example, L_4 and L_5. Once the distractor **100** is in place, if fusion alone is to be performed, then the extended outer sleeve **1000** having both anterior and posterior extension members **1020** and **1022** is utilized. The extended outer sleeve **1000** is placed over the distractor **100** such that the posterior extension member **1022** is positioned at the posterior aspect of the spine and the anterior extension member **1020** is positioned at the anterior aspect of the spine. Once the extended outer sleeve **1000** is in place, the distractor **100** is removed. Alternatively, it is appreciated that the "Lateral Method" may be performed without the use of a distractor. Instead, the extended outer sleeve **1000** may be inserted from the lateral aspect of the spine directly since the extension members **1020** and **1022** function to distract the adjacent vertebrae L_4 and L_5 to restore and maintain the normal angular relationship of those vertebrae L_4 and L_5.

If the implant to be inserted has surface irregularities such that there is a major diameter (including the surface irregularities) and a minor diameter (excluding the surface irregularities), then an inner sleeve **1040** similar to the inner sleeve **242** described above, may be inserted into the extended outer sleeve **1000**. The inner sleeve **1040** functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of such implant as described in detail above in reference to an inner sleeve **1040**. A drill **250**, described above, is inserted into the inner sleeve **1040** and is used to drill the vertebrae with the inner sleeve **1040** providing a more intimate fit to the drill **250**, than the larger bore of the extended outer sleeve **1000** could have alone and thus more precisely controlling the path of the drill **250**. The inner sleeve **1040** and the drill **250** may be removed from the extended outer sleeve **1000** together thus trapping and removing much of the debris produced by the actual drilling. It is appreciated that in the alternative, a drill (not shown) may be used such that the distal bone engaging portion has an outside diameter generally corresponding to the minor diameter of the implant and more proximally, a shaft portion with a larger diameter generally corresponding to the major diameter of the implant. An implant I may then be inserted according to the method described above. If the implant to be inserted does not have a major and minor diameter, then no inner sleeve is required, and the drill **250** having a diameter corresponding with the diameter of such an implant may be inserted directly into extended outer sleeve to drill the vertebrae L_4 and L_5.

While not considered the preferred method under most circumstances it is nevertheless anticipated that one could drill the described hole across the disc space and into each of the adjacent vertebrae from the lateral aspect of the spine and in at least a partially side to side direction through the extended outer sleeve and then remove the extended outer sleeve and insert at least one spinal implant also from the lateral aspect of the spine and in an at least a partially side to side direction and with or without the use of some form of spinal distractor. In which circumstance the use of an inner sleeve is of less importance than that the size of the opening created is sufficient such that it is possible to insert the implant. To that end and independent of whether the extended outer sleeve is left in place for implant insertion, and whether an inner sleeve is used during drilling it is anticipated and should be appreciated that the extended outer sleeve and opening may be of a variety of shapes and that the creation of spaces of varied shapes across a disc and within the spine may be achieved by use of an instrument appropriate for the surgical removal of spinal material, such as a chisel or a router, and with or without the use of a drill, and/or an inner sleeve, and/or an extended outer sleeve; and with the essential element being that the space within the spine is being created across a disc intermediate two adjacent vertebrae from the lateral aspect of said disc and at least in part in a from side to side direction and that an implant is then inserted also from the lateral aspect of said disc which implant occupies at least in part said space, engages at least in part each of the vertebrae adjacent said disc space and comes to lie in an at least partially side to side direction across said disc space.

Referring to FIGS. **29** and **30**, the implant I and J are shown inserted across the disc spaces D between vertebrae L_3, L_4 and L_5, respectively. FIG. **30** is a top sectional view along lines **30-30** of FIG. **29** showing the area of contact of the implant I and the vertebrae L_4. It can be seen from FIG. **30** that the implant I has a true lateral orientation with respect to the vertebra L_4, such that there is a great area of contact between the implant I and the vertebra L_4.

Referring to FIG. **30**A, a top sectional view of a vertebra similar to FIG. **30** is shown illustrating the area of contact of the implant I and the vertebrae L_4 when the implant I is inserted with the "Lateral Method" of the present invention from a slightly anterior position (anterolateral) along the Lateral aspect of the spine and in an at least partially side to side direction.

Referring to FIGS. **31** and **32**, illustrating the prior art method, two implants **1050** and **1052** are inserted from the anterior or posterior aspect of the spine so that they are oriented in an anterior to posterior direction across the disc space D and vertebrae L_4 and L_5. It can be seen that implants **1050** and **1052** must have a much smaller diameter than implant I to fit within the width of the spine and therefore have very small areas of engagement to the vertebrae themselves as most of the diameter of the implants is used in just spanning across the height of the disc before contacting said vertebrae. FIG. **32** is a top sectional view along lines **32-32** of FIG. **31** showing the area of contact of the two spinal implants **1050** and **1052** and the vertebra L_5.

Referring to FIG. **33**, a top sectional view showing the area of contact of a cylindrical spinal implant **1090** having the same diameter as implant I shown in FIG. **30**, inserted from the anterior to posterior direction across the vertebra L_5 is shown and seen to have by necessity a much shorter length.

Referring to FIGS. **30** and **32-33**, it can then be appreciated that an implant I inserted from the lateral aspect of the spine may have a diameter almost as great as the depth of the spine from front to back at that location unlike two implants such as implants **1050** and **1052** inserted side by side from front to back or the reverse where each implant can have a diameter no greater than one half the width of the spine at that level. It can further be appreciated that while the height of the disc space

itself hardly affects the area of contact of the single large implant I with the adjacent vertebrae, it substantially effects the area of contact of the two implants **1050** and **1052** inserted in the front to back directions side by side. Further, as the lumbar vertebrae and discs are much wider from side to side then they are deep from front to back, it can be appreciated that when single implants of the same diameter are inserted across a given lumbar disc, the laterally inserted implant I may be of a much greater length and thus have more area of contact, for stability and fusion than implant **1090** inserted from anterior to posterior.

Referring to FIG. **34**, a segment of the spinal column having single implants **1095** and **1096** inserted from front to back at adjacent disc levels between three vertebrae V_{1-3} is shown. As it can be seen in FIG. **34**, it is generally not possible to increase the diameter of singular implants inserted from front to back without risking severe structural and vascular damage to that area of the spine. Implants **1095** and **1096** each have a diameter that is substantially greater than the diameter of implant **1090**, such that implants **1095** and **1096** could in theory have a greater area of contact with the adjacent vertebrae than it **1090**. However, in application, as a result of the larger diameter of the implants **1095** and **1096**, a large portion of bone from the adjacent vertebrae would have to be removed to accommodate the large diameter of each of the implants **1095** and **1096** which would significantly weaken the structural integrity of those vertebrae. This is especially a problem when as shown in FIG. **34**, implants **1095** and **1096** are inserted at adjacent disc levels such that the intermediate vertebrae V_2 would be cut in half to form a "butterfly" pattern resulting in the complete loss of the structural integrity of vertebrae V_2.

Thus, the implant I of the present invention inserted laterally provides for greater surface area of contact, the largest volume of fusion promoting material, and the greatest mechanical engagement and thus stability, and is therefore an improvement upon other methods of implant insertion in facilitating a successful fusion.

Referring to FIG. **35**, an alternative embodiment of the extended outer sleeve is shown and generally referred to by the numeral **1100**. As only a single relatively small incision (approximately three inches or less) is required through the abdominal wall of the patient to perform the procedure for the fusion of two vertebrae adjacent a disc space in the lumbar spine, it is anticipated that the surgeon may prefer to perform the method of the present invention under direct vision, without the need for an endoscope. In such a circumstance, a convertible extended outer sleeve **1100** may be used. The convertible extended outer sleeve **1100** may be similar in structure to the extended outer sleeve **1000**, except that it comprises a hollow tubular member **1102** that is disengageable from the distal end portion **1104** of the convertible extended outer sleeve **1100**. As shown in FIG. **35** the extended outer sleeve **1100** has a detachable hollow tubular member **1102**. The vertebrae engaging distal end portion **1104** may be as shown in FIG. **35** or may be similar to the distal end shown previously in FIG. **7**A, such that the convertible extended outer sleeve **1100** may be useable throughout the spine.

The convertible extended outer sleeve **1100** is inserted in the disc space D and the adjacent vertebrae L_4 and L_5 as described above for the extended outer sleeve **1000**. Once the extension member **1120** is seated in the disc space D and the prongs **1112** and **1114** are engaged to the vertebrae L_4 and L_5, the hollow tubular member **1102** may be dissociated from the distal end portion **1104** which remains engaged to the vertebrae L_4 and L_5. In this manner, if an incision is made to access the spine directly, the surgeon may access the disc space D through the distal end portion **1104** which is closer to the spine, without having to pass through the entire length of the convertible extended outer sleeve **1100**. With the distal end portion **1104** in place, the vertebrae remain distracted and aligned, and since the hollow tubular member **1102** has been removed, it is then possible for the surgeon to work in and around the spine under direct vision. The shortened distal end portion **1104** of the convertible extended outer sleeve **1100** left protruding from the adjacent vertebrae may be selected to be of a length such that it still serves to offer some protection to the large blood vessels which are safely positioned outside of the remaining working channel. Alternatively it can be of any length so as to fulfill the surgeon's purposes. The hollow tubular member **1102** may be re-engaged to the distal end portion **1104** for inserting an implant I in the manner described above.

In the specific embodiment of the convertible extended outer sleeve **1100**, the distal end portion **1104** has a single extension member **1120** and two prongs **1112** and **1114** positioned approximately 120 degrees from the extension member **1120** for engaging the two adjacent vertebrae L_4 and L_5, for the purpose of allowing the surgeon direct access to the spinal canal. Thus, if a discectomy is to be performed, an extended outer sleeve having a single anterior intradiscal extended member **1120**, but without a posterior extended member, and with two vertebrae engaging prongs **1112** and **1114** may be used.

It is appreciated that for surgery on the thoracic spine, while the method described above wherein the entire procedure is performed through the extended outer sleeve **140** is preferred, it is also possible to utilize the convertible extended outer sleeve **1100** when a full thoracotomy is made to access the thoracic spine without having to work through the entire length of the extended outer sleeve, in this manner the surgeon may directly visualize and access the surgical site.

Further, combining the features of the absence of any posterior intradiscal extended member with the convertible extended outer sleeve **1100** permits easy and direct access to the spinal canal for removal of any diseased discal material.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

I claim:

1. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

2. The method of claim **1**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

3. The method of claim **2**, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

4. The method of claim **1**, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

5. The method of claim **4**, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

6. The method of claim **4**, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

7. The method of claim **1**, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

8. The method of claim **1**, wherein said fusion implant is provided in combination with fusion promoting substances.

9. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

10. The method of claim **9**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

11. The method of claim 10, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

12. The method of claim 9, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

13. The method of claim 12, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

14. The method of claim 12, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

15. The method of claim 9, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

16. The method of claim 9, wherein said fusion implant is provided in combination with fusion promoting substances.

17. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having at least two elongated portions for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, said length of each of said at least two elongated portions being greater than the width and the thickness of said at least two elongated portions, each of said at least two elongated portions have a cross section through the width and the thickness and perpendicular to the length of said at least two elongated portions, respectively, each cross section of said at least two elongated portions having a convex exterior surface, said convex surfaces of each of said at least two elongated portions having the same curvature;

positioning said third surgical instrument such that at least part of one of said at least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

18. The method of claim 17, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

19. The method of claim 18, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

20. The method of claim 17, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

21. The method of claim 20, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

22. The method of claim 20, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

23. The method of claim 17, wherein said fusion implant is provided in combination with fusion promoting substances.

24. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said sec-

ond surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

withdrawing said second surgical instrument and said first surgical instrument from the body; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

25. The method of claim **24** further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

26. The method of claim **25** wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

27. The method of claim **24** further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

28. The method of claim **27** wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

29. The method of claim **27** wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

30. The method of claim **24** wherein said fusion implant is provided in combination with fusion promoting substances.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,251,997 B2
APPLICATION NO. : 13/306583
DATED : August 28, 2012
INVENTOR(S) : Gary Karlin Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page 1, Item (56) References Cited, U.S. Patent Documents:
Column 2, line 3, change "Moreira" to -- De G. Moreira --.

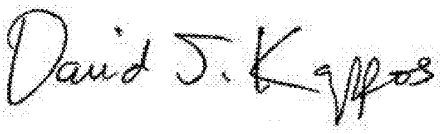
Title Page 3, Item (56) References Cited, Foreign Patent Documents:
Column 1, line 64, change "6/1982" to -- 6/1986 --.

Title Page 3, Item (56) References Cited, Other Publications:
Column 2, line 20, change "12/655/178" to -- 12/655,178 --;
Column 2, line 23, change "on Bone" to -- of Bone --;
Column 2, line 41, change "Sincipitai" to -- Sincipital --; and
Column 2, line 65, change "61.793-794" to -- 61:793-794 --.

Title Page 4, Item (56) References Cited, Other Publications:
Column 1, line 6, change "Transiation" to -- Transition --;
Column 1, line 37, change "Alloplastic, Materials" to -- Alloplastic Materials --;
Column 1, line 59, change "Medics" to -- Medica --;
Column 1, line 65, change "Paul M," to -- Paul M. --;
Column 1, line 66, change "114-.122" to -- 114-122 --;
Column 2, line 4, change "et al.:" to -- et al.; --;
Column 2, line 6, change "3-20)," to -- 3-20, --;
Column 2, line 20, change "Retropedtoneal" to -- Retroperitoneal --;
Column 2, line 22, change "5,7" to -- 5.7 --;
Column 2, line 25, change "1998,." to -- 1998. --;
Column 2, line 35, change "45:628-6387" to -- 45:628-637 --;
Column 2, line 53, change "Willberger" to -- Wiltberger --; and
Column 2, line 56, change "Acronex" to -- AcroFlex --.

Title Page 5, Item (56) References Cited, Other Publications:
Column 1, line 36, change "et al.'s l" to -- et al.'s --;

Signed and Sealed this
Eighth Day of January, 2013



David J. Kappos
Director of the United States Patent and Trademark Office

CERTIFICATE OF CORRECTION (continued)
U.S. Pat. No. 8,251,997 B2

Column 1, line 69, change "6,946,933" to -- 6,945,933 --;
Column 2, line 10, change "08cv1 512-" to -- 08cv1512- --;
Column 2, line 21, change "B,10," to -- B.10, --;
Column 2, line 25, change "8.22," to -- B.22, --;
Column 2, line 28, change "M.D.." to -- M.D., --;
Column 2, line 32, change "M,B,A.," to -- M.B.A., --;
Column 2, line 36, change "iInc.'s" to -- Inc.s --;
Column 2, line 53, change "pages" to -- pages; --; and
Column 2, line 66, change "Sep. 20" to -- Sep. 29 --.

Title Page 6, Item (56) References Cited, Other Publications:
Column 1, line 56, change "Bono" to -- Bone --;
Column 1, line 64, change "Thoracotorny" to -- Thoracotomy --;
Column 2, line 13, change "Acrorned" to -- Acromed --;
Column 2, line 15, change "*Spione*" to -- *Spine* --; and
Column 2, line 26, change "Structrual" to -- Structural --.

Title Page 7, Item (56) References Cited, Other Publications:
Column 1, line 9, change "inc.'s" to -- Inc.'s --;
Column 1, line 13, change "Worksheet;" to -- Worksheet, --;
Column 2, line 5, change "Nuvasive." to -- Nuvasive, --;
Column 2, line 8, change "7;470;236" to -- 7,470,236 --;
Column 2, line 11, change "Sofarnor" to -- Sofamor --;
Column 2, line 13, change "at al." to -- et al. --; and
Column 2, line 14, after "Disclosure" insert -- of Asserted --.

CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on February 19, 2015. All counsel of record were served via CM/ECF on February 19, 2015.

/s/ Craig E. Countryman
Craig E. Countryman

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that NuVasive's Opening Brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contain 9,893 words, as determined by Microsoft Word.

Dated: February 19, 2015

/s/ Craig E. Countryman

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